The London School of Economics and Political Science

Understanding the Impact of Protection on Manufacturing Efficiency Levels and Relative Pharmaceutical Prices
Evidence from Egypt's Generics Pharmaceutical Industry (1993-2008)

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DECLARATION

I certify that the thesis I have presented for examination for the PhD degree of the London School of Economics and Political Science is solely my own work other than where I have clearly indicated that it is the work of others (in which case the extent of any work carried out jointly by me and any other person is clearly identified in it).

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ABSTRACT

This thesis aims at contributing to the literature on industrial policy by investigating patterns of 'association' between trade and industrial policies, the country's national pharmaceutical policy (including pricing), the pre-January 2005 intellectual property rights regime, productivity and productivity growth in the Egyptian generics pharmaceutical sector. This thesis presented evidence that positive total factor productivity (TFP) growth can be observed under the auspices of a protectionist regime, however, there is a need to revisit pharmaceutical regulatory protectionism, as it impacts negatively on export growth and on fair pharmaceutical prices.

Under the auspices of what can be categorised as a protectionist regulatory regime, this thesis examined trends in TFP growth in 13 of Egypt's pharmaceutical generics firms, which account for 50 percent of the generics market by value. Empirical results indicated that the best-practice firm in terms of TFP change belonged to the private sector, while the laggard firm belonged to the state-owned public business sector. Empirical results indicated that mean TFP change for the sample firms throughout the study period 1993-2005 (1.01) exceeded the mean TFP change for all Egyptian industries (0.75), and that there was evident disassociation or weak correlation -at best- between productivity growth and the degree of export orientation.

In light of both the absence of significant generics import competition in Egypt, it has been found that prices of generics were *atypical* in terms of exceeding standard worldwide generic-to-originator price ratios. Generic diffusion did not significantly bring down average prices, while an evident wedge was observed between the market shares of the most sold generics versus the least-priced generics to the advantage of the former.

As a result of enforcing pharmaceutical product patent protection as of January 2005, the price-related impact of the TRIPS Agreement in the domain of Egypt's top 42 therapeutic classes by market value (50 percent of the market), has been put in the range of LE 479 million.

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LIST OF ACRONYMS AND ABBREVIATIONS

CBO: Congressional Budgetary Office
CCO: Curative Care Organization
DEA: data envelopment analysis
DMU: decision-making units
EDA: Egyptian Drug Authority
EMRs: exclusive marketing rights
ERSAP: Economic Reform and Structural Adjustment Program
FDA: Food and Drug Administration
FDI: Foreign Direct Investment
FHF: Family Health Fund
FHU: Family Health Unit
GM: governed market
GMP: good manufacturing practices
GOPCA: General Organization for Pharmaceuticals, Chemical and Medical Appliances
CAPA: Central Administration for Pharmaceutical Affairs
HAI: Health Action International
HIO: Health Insurance Organization
HSRP: Health Sector Reform Program
IMS: Intercontinental Medical Statistics
IND: claimed investigational for a new drug
IND: investigational for a new drug
IPRs: Intellectual property rights
IPTs: Intellectual Property Rights
ISI: import substitution industrialisation
ISI: import substitution industrialisation
LDCs: less developed countries
LE: Livre Égyptienne or Egyptian Pound
LPG: the lowest price generic
MENA: Middle East and North Africa
MOF: Ministry of Finance
MOH: Ministry of Health
MSG: most sold generic equivalent
NDA: new drug application
NDP: national drug policy
NHA: National Health Accounts
NICs: Newly Industrialised Countries
NMEs: new molecular entities
NODCAR: National Organization for Drug Control and Research
NORCB: National Organisation for Research and Control of Biologicals
ODP: Open Door Policy
OTC: over the counter
PhRMA: Pharmaceutical Research and Manufacturers of America
R&D: research and development
TFP: Total Factor Productivity
THO: Teaching Hospitals Organization

TNCs: transnational companies
TRIPS: Trade Related Aspects of Intellectual Property Rights
UNCTAD: United Nations Conference on Trade and Development
USD: United States Dollar
USTR: United states Trade Representative
WHO: World Health Organization
WTO: World Trade Organisation

1. INTRODUCTION TO THE RESEARCH

1.1 Introduction

To date, and within the confines of the large body of development literature, the debate concerning the nature and scope of government involvement in economic activity has perhaps been the longest standing. This thesis has been motivated by the debate concerning one important facet of government intervention in the economy, namely industrial policy. The importance of this debate stems from the fact that the success/failure of industrial policies as practiced in developed as well as developing nations has invariably contributed to shaping their growth outcomes.

By examining the growth trajectory and performance attributes of Egypt's generics pharmaceutical industry, I should be able to provide one interesting avenue to contribute to the debate concerning industrial policy. In this thesis, I will be making a case in favor of revisiting the country's industrial policy as it impacts the generics pharmaceutical industry. The objective of a revised industrial policy is to sharpen the capabilities of local companies to withstand competition on local as well as on export markets, as well as to improve the levels of efficiency. Achieving these two objectives should better prepare Egypt's generics pharmaceutical industry to meet the challenges of the immediate future.

What renders the case study of Egypt's generics pharmaceutical industry relevant to the debate on industrial policy is that the development and expansion of pharmaceutical productive capacity has occurred within the context of protective non-tariff regulatory trade barriers, which have historically kept generics import competition at bay. While several episodes of trade liberalization have occurred following the endorsement of an Open Door Policy (ODP) in 1974, eventually lowering tariff levels and eliminating non-tariff barriers to trade shielding Egyptian industry -particularly under the framework of World Trade Organisation (WTO) commitments during the second half of the 1990s- the pharmaceutical industry stands out as being subject to relatively rigid regulatory non-tariff trade barriers, which have largely isolated local manufacturers of generics from import competition.

In addition, the case study of Egypt's generics pharmaceutical industry is equally interesting because of the fact that the enforcement of higher standards of intellectual property rights (IPRs) has been changing the outlook for the pharmaceutical industry. In 1995, Egypt became a founding member of the WTO and a signatory to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In January, 2005, and in conformity with the TRIPS Agreement, pharmaceutical product patent protection was enforced for the first time ever in Egypt. Prior to this date, the Egyptian pharmaceutical industry has been thriving under the auspices of an IPRs regime, which excluded pharmaceutical products from patentability.

Currently, issues of concern in policy circles have been related to the prices of pharmaceutical products in Egypt -particularly with higher standards of IPRs paving the way for the gradual increase in the relative prices of new pharmaceutical products coming to the market- as well as the efficiency and competitiveness of this industry. In close connection, two important studies concerning the affordability of pharmaceutical products in Egypt (WHO and HAI, 2004), as well as the competitiveness of the pharmaceutical industry (ADE/DOL, 2004) have cautioned that essential drug prices are actually higher than they need be, making essential medicine 'unobtainable' for many, and that the pharmaceutical industry has not been contributing much to national economic growth, with sector performance having been largely stagnant.

In light of the fact that generics import competition on the Egyptian market has been a fairly new phenomenon, and that the enforcement of pharmaceutical product patent protection is also an equally new phenomenon, historically local companies have been operating in an environment which tended to increase their market power vis-à-vis other low cost manufacturers of generics, as well as subsidiaries of research-based companies with manufacturing presence in Egypt. In other words, local companies have enjoyed operating within a captive local market, while at the same time being legally able to manufacture products which were still protected by patents on other world markets. Commitment to strengthen the country's IPRs regime, under the framework of the TRIPS Agreement, as well as the gradual increase in the market share of imported generics are two

key developments, which promise to change the nature of the competition matrix on Egypt's pharmaceutical market. The Egyptian pharmaceutical industry is, therefore, a prime candidate to be affected in a major way as a result of two key developments: the country's process patent regime giving way to a product patent regime since January 2005, and the gradual increase in generic import penetration, which has also been levying significant competitive pressure on the local segment of this industry.

Taking into consideration the essential nature of pharmaceutical products, the motivation to select Egypt's generics pharmaceutical sector as the case study of this thesis is primarily two pronged. On the health policy front, while concern regarding the affordability of new patent-protected pharmaceuticals in Egypt has been accentuated in the aftermath of the TRIPS Agreement, an equally important concern, which has been -more often than not- overshadowed, is related to the affordability and relative prices of generics pharmaceuticals in Egypt. On another front, this concern is directly tied up to the industrial policy issue of efficiency levels exhibited by Egypt's generics industry.

A pertinent question, which has been judged to be worth addressing, has been related to the extent to which Egyptian consumers have been paying relatively higher than average prices for locally manufactured generic products. On the front of industrial and regulatory policies, it became important to probe deeper into whether higher than average prices have been associated with an inefficient industry manufacturing at high cost, or with an efficient industry that has exploited the protectionist regulatory setting to its favour by charging higher than average prices. The enforcement of higher standards of IPRs in Egypt renders generics a life-saving line for low-income consumers, and hence from a policy perspective, it becomes not only important but mandatory to examine efficiency and market dynamics of this important segment of Egypt's pharmaceutical market.

Among the key reasons why the pharmaceutical industry was selected as the subject matter of this thesis has been also related to the associated human factor. Unlike other products of manufacturing industries, pharmaceuticals are correctly described as "life or death" products. In a country where 22 percent of the population are categorized as poor, and

another 6 percent as ultra-poor (Egypt Human Development Report, 2010),[1] and where private out-of-pocket expenditure on drugs stands as high as 68 percent of total expenditure on drugs, affordability and access to health care in general and pharmaceuticals in particular have persevered as major policy concerns. With the partial coverage of social health care insurance, a significantly large segment of Egypt's masses remains vulnerable to potential catastrophic health care expenditure and impaired access to medicine.

1.2 Research Focus

In light of the above backdrop, this thesis has been motived to contribute to the academic debate concerning industrial policy by examining patterns of 'association' between trade, industrial and health policies (regulatory protectionism), the ruling pre-January 2005 IPRs regime, pricing behaviour, productivity and productivity growth in the Egyptian generics pharmaceutical sector. In addition, this thesis has also taken the first attempt to quantify the cost to consumers as a result of enforcing a 20-year period of pharmaceutical product patent protection in conformity with the TRIPS Agreement.

The study period extends between 1993 and 2008. This period spans a series of policy changes, both at the macroeconomic as well as the pharmaceutical sector levels. On the macroeconomic front, the early 1990s ushered an economic reform and structural adjustment program (ERSAP), which introduced far reaching institutional as well as regulatory change to the pharmaceutical sector. The 1990s and beyond also brought some of the most important of legislative changes in the history of Egypt's pharmaceutical industry, namely the commitment to enforcing a 20-year period of pharmaceutical patent protection in the aftermath of the TRIPS Agreement, and the associated transitional institutional changes, which were eventually completed in January 2005.

This thesis attempts to contribute to a diverse set of literature in four key areas. First, the fact that some of the privately owned local firms exhibit relatively high export-to-output

[1] According to the 2010 Egypt Human Development report, a person who spends less than LE1,648 per year (LE134 per month) in Egypt in 2008 was categorized as extremely poor, and a person who spent less than LE2,223 (LE185 per month) was categorized as poor.

ratios indicates that there have been efficiency gains in this sector sufficient enough for these companies to compete in world markets. The estimation of firm-level productivity growth under a protectionist regulatory regime is one important avenue to contribute to the literature on industrial policy (evaluating productivity growth under a protectionist regulatory regime).

Second, this thesis also endeavours to verify whether there has been evidence of firm-level productivity dispersion in relation to ownership and output orientation in Egypt's generics pharmaceutical industry. The answer should provide guidance to the pace and nature of privatisation policies (to date the state maintains majority ownership in the 11 public-business sector pharmaceutical companies), as well as to policies which aim at soliciting increased export-orientation.

To date, there has been no empirical work regarding the productivity of Egyptian pharmaceutical firms. Studies regarding productivity in Egypt have traditionally focused on analysing sources of *aggregate* economic growth using the traditional total factor productivity (TFP) (Kheir-El-Din and Moursi, 2003), as well as examined TFP in Egypt at the economy-wide level (Kamaly, 2007). With regards sector specific studies, Abdellatif (2004) looked into the course of growth of the manufacturing sector in Egypt at large, exploring its sources of growth over the past 50 years. Galal and El-Megharbel (2005) estimated TFP for 16 industries comprising the manufacturing sector in Egypt over the period 1980-2000 to answer the question of whether or not industrial policy in Egypt made a difference in the performance of different industries. In the absence of longitudinal microdata concerning *any* of Egypt's manufacturing sectors, this study should hopefully open the way to similar studies at the firm-level, particularly in one of the country's strategic and most socially sensitive of manufacturing activities.

Third, to-date, there has been no evaluation regarding relative prices on the Egyptian pharmaceutical market. In major world markets, relatively standard price ratios exist between innovator and generic products, as well as between generics. By providing an evaluation regarding the consistency of price ratios on the Egyptian market with standard

world ratios, this thesis should be able to contribute to the evaluation of the extent to which the country's pharmaceutical policy -including pricing- has been successful in terms of ensuring the prevalence of fair prices to consumers. By undertaking this analysis, the thesis will be able to contribute to the body of literature which examines the nature and determinants of relative prices on pharmaceutical markets.

Fourth, an important contribution of this thesis will be in the domain of quantifying the impact of the TRIPS Agreement in terms of elevated cost to consumers on Egypt's pharmaceutical market. To date, there are no studies that have attempted to quantify the impact of enforcing pharmaceutical product patent protection on market dynamics in Egypt using real market data. Empirical results should be valuable from a policy perspective, particularly in terms of throwing light on the nature of policy interventions, which may be needed in order to protect low-income consumers. The majority of these consumers mainly meet their pharmaceutical needs on the basis of out-of-pocket expenditure. The results will contribute to the body of literature which has endeavoured to evaluate the impact of the global harmonisation of IPRs in the domain of the pharmaceutical industry in emerging markets.

1.3 Research Questions

Against the above background, the following set of research questions will be addressed in the thesis:

- To what extent have mechanisms used to protect and regulate the Egyptian pharmaceutical industry been associated with productivity growth?
- To what extent is there evidence of productivity dispersion in the Egyptian pharmaceutical industry in accordance to ownership, and output orientation?
- How far and in what ways have the regulatory framework(s) governing this industry allowed local generics companies to charge higher than average prices compared to other world markets?
- What has been the impact of strengthening the country's IPRs regime in conformity with the TRIPS Agreement on pharmaceutical price levels in Egypt, the associated cost to consumers, as well as on the market shares of key players?

1.4 Research Design

The key objective of this thesis is to be able to contribute to the debate on industrial policy, through empirical evidence concerning productivity levels exhibited by Egypt's generics pharmaceutical industry under the auspices of a protectionist regulatory regime.

The review of the literature on industrial policy, presented the starting point for the research, as well as the 'back-bone' of the thesis. The review of the salient characteristics of the pharmaceutical industry followed, with the objective of highlighting the key differences between research-based and generics pharmaceutical manufacturers. It is against this background which details how and why similar as well as dissimilar pharmaceutical manufacturers operate on the world production and trade scenes, that the growth trajectory and performance of Egypt's generics pharmaceutical sector can be examined as well as evaluated.

The core components of the industrial policy regime which ruled in Egypt during the study period are highlighted, in conjunction with the key performance attributes of this industry (output growth, employment creation, export performance and R&D strategies). The pharmaceutical industry distinguishes itself from other sectors of manufacturing activity by virtue of operating under the auspices of two policy and regulatory regimes. One is the industrial policy regime, while the other is the health policy regime. The exposé of the key features of Egypt's health care sector, as well as the national drug policy became an integral part of the research design, having served the purpose of contextualising the research questions by highlighting how pharmaceutical prices are being set, as well as how pharmaceutical expenditure is being shouldered.

Secondary sources were mostly relied on; however, primary sources such as minutes of board meetings of local Egyptian pharmaceutical companies as well as unpublished government documents related to the impact of policy change during the initial period of the ERSAP were collected and reviewed in order to gain insight to the nature of the debate

which was taking place between the various stakeholders within industry and in policy circles concerning the industrial policy regime.

During the literature review phase as well as throughout the study period, a set of interviews were arranged for to complement the viewpoints expressed in the literature regarding the growth trajectory of Egypt's pharmaceutical sector, with the reality on the ground. Interviewees were approached on the basis of their presence in the policy circles as well as within industry. Interviews were chosen to be conducted in an unstructured manner, whereby the nature of research was first explained, after which the interviewees provided their viewpoints regarding the various issues and research questions being raised. A list of interviewees and their professional affiliations is provided in Annex 1.

In order to examine pharmaceutical market dynamics, the Intercontinental Medical Statistics (IMS) database for Egypt provided most of the data needed.[2] However, because IMS data for Egypt is significantly large and embraces a wide range of therapeutic classes, a stratification of the Egyptian pharmaceutical market was conducted. The IMS data frame was organized by categories into separate therapeutic "strata". These strata which have been selected for analysis were based on the two criteria of embracing essential rather than over-the-counter or lifestyle drugs, as well as accounting for the largest shares of the pharmaceutical market.

For the estimation of TFP growth, initially all local generics pharmaceutical companies which have been in operation before 1991 have been approached for data collection. Of the 16 companies that have been operative before this date, 13 companies accepted to provide the necessary data. As such, the sample is based on the non-probability 'opportunity' sampling approach, whereby only the interested companies became part of the study. The appropriateness of non-probability sampling as well as its limitation will be covered in more detail in Chapter Five.

[2] IMS Health is a specialised market research company, which is the leading provider of reports concerning pharmaceutical retail sales in more than 70 countries, based on regular audits of retail pharmacies.

1.5 Research Methodology and Sources of Data

The research questions posed in this thesis required a multi-pronged methodological approach.

To evaluate efficiency levels exhibited by Egypt's generics pharmaceutical industry, an estimation of trends regarding total factor productivity (TFP) growth in 13 of this sector's largest and oldest generics pharmaceutical firms will be conducted. Data envelopment analysis (DEA), the non-parametric, frontier methodology, is relied upon to obtain the Malmquist productivity index for the sample firms, which account for 45 percent of Egypt's generics market by value. Best-practice firms and laggard firms in the three aspects of efficiency change, technical change and TFP change have been identified. The estimation of TFP growth is based on a rich set of primary panel data obtained directly from the sample companies.

In order to evaluate pharmaceutical pricing dynamics in Egypt, competition taking place between products manufactured by various players on the manufacturing and trade scenes in Egypt will be evaluated. Products examined fall within the domain of some 21 molecules, covering a wide range of therapeutic classes. The list of molecules -originally 30- has been featured in the World Health Organization (WHO) and Health Action International (HAI) study (2006) concerned with the international comparison of chronic disease medicines. Access to data from IMS for Egypt has allowed for the assessment of market dynamics during a five-year study period for which data was available. Special emphasis has been awarded to the issue of relative prices as well as the impact of the TRIPS Agreement in terms of increased cost to consumers.

Quantifying the impact of the TRIPS Agreement on Egypt's pharmaceutical market was based the identification of new molecules placed on the Egyptian pharmaceutical market by research-based companies, that have not been facing generic competition. This scan covered Egypt's top-42 therapeutic classes by market value (50 percent of the market) and was undertaken in conjunction with information regarding the patentability status of new molecules placed on Egypt's market, in one of the world's key markets, namely the United

States of America (USA). The respective market shares for these new molecules/products in Egypt, and the associated cost to consumers in Egypt have been examined.

1.6 Thesis Structure

Following the introductory Chapter, Chapter Two presents a review of the literature on industrial policy. The literature on industrial policy embraces a wide continuum of policy options, with free trade and protectionism falling on its extreme poles. Various incentive measures provided by governments to solicit certain outcomes also fall on this wide continuum. How and why have the policy choices made by governments differentially elevated some of the developing nations to the status of newly industrialized countries (NICs), while others have lagged behind, is perhaps the most important of insights to be derived from this body of literature. Chapter Two also presents the concept of efficiency, as well as the underlying reasons behind differential efficiency/productivity outcomes among various countries/ industries/ firms.

In Chapter Three, the salient characteristics of the pharmaceutical industry are presented, with the objective of highlighting the key differences between research-based and generics pharmaceutical manufacturers as well as the structure of the world pharmaceutical market, in terms of both production and trade. Chapter Three highlights the fact that some developing countries such as India, have successfully managed to emerge as key players on the pharmaceutical production and trade scenes, while others have lagged behind (Egypt being a case in point). Chapter Three also examines in detail the growth trajectory of Egypt's generics pharmaceutical industry against the nature of the industrial policy regime(s) which ruled during the study period(s). The key objective of Chapter Three is to provide the background against which the research question concerning the extent to which mechanisms used to regulate and protect the Egyptian generics pharmaceutical industry have been associated with productivity growth.

The review presented in Chapter Three provided evidence that since the formative years of the Egyptian generics pharmaceutical industry, and passing through different policy and regulatory regimes, the focus as well as the key criteria for success for this industry has

primarily been on increasing the levels of self-sufficiency, in what has been regarded as a strategic sector. The various shifts in economic policy direction, as well as episodes of institutional and regulatory reforms have consistently defaulted in shifting the relatively excessive inward orientation of this industry. Unlike the majority of manufacturing industries in Egypt, which have seen protective tariff as well as non-tariff trade barriers systemically brought down during various intervals, the perseverance of non-tariff regulatory barriers shielding the generics pharmaceutical industry in Egypt has practically isolated this industry from import competition. Chapter Three also documents the failure to transcend the boundaries of engaging in sheer pharmaceutical formulation activities by venturing towards expanding R&D capabilities on behalf of the local generics pharmaceutical industry in Egypt. Evidence presented also indicated that Egypt's generics pharmaceutical industry has not been a key contributor to job creation in what is predominately a labor surplus economy. Egypt's generics pharmaceutical industry has, therefore, not been a key contributor to job creation, to export growth or to technological advancement. This industry has, nonetheless, been closing-down on the levels of self-sufficiency. The important question which was addressed further on was related to whether or not increasing the levels self-sufficiently have been attained while at the same time achieving respectable levels of manufacturing efficiency.

Chapter Three documents the extent to which the key changes in Egypt's industrial policy regime during the study period have been primarily concerned with addressing institutional as well as regulatory concerns such as public sector reform, privatisation, and price liberalisation. A key limitation of Egypt's industrial policy as implemented within the domain of the generics pharmaceutical sector was that it failed to clearly tie up regulatory protection to performance indicators such as exporting as well as advancing technological capabilities. The outcome of this policy pitfall was that Egyptian generics companies have been outpaced by their counterparts in India, which have emerged at a far more advantageous position when it comes to competing on what is turning to be a highly aggressive global pharmaceutical market. India's generics companies have assumed this advantageous position as a result of the government creating a home environment which has forced firms to improve their technological capabilities (Mourshed, 1999).

Chapter Four presents a review of the key components of the national drug policy in Egypt. The objective was to throw light on the characteristics of the pharmaceutical regulatory regime, which influence relative prices on the market. Chapter Four also examined the pharmaceutical industry in the context of the Egyptian health care system and how it "interacts" with it, both from a formal perspective (covering the costs and purchasing of medicines by the state/health system) and from the perspective of patients through direct purchases outside the remit of the health system. The objective has been to place the research question concerning relative price levels as well as the related findings in the context of who shoulders the burden of pharmaceutical expenditure in Egypt. Among the key findings of this chapter is that while the Egyptian government has been endeavoring to extend the benefits of social health insurance to the maximum number of beneficiaries, Egypt's health care system has remained largely inequitable, leaving close to half of the country's population to be fully vulnerable to potential catastrophic health care expenditure.

Chapter Five attempted to address the research questions regarding the extent to which mechanisms used to regulate and protect Egypt's generics pharmaceutical sector have been associated with productivity growth as well as the nature of productivity dispersion in accordance to ownership and output orientation. To be able to answer these research questions, Chapter Five began by presenting the methodology to estimate TFP growth in Egypt's generics pharmaceutical industry during the period 1993-2005. The details of the non-parametric, frontier methodology known as data envelopment analysis (DEA) to obtain the Malmquist productivity index at the firm-level for a representative sample of firms operating in the Egyptian pharmaceutical sector is presented. The key empirical findings indicated that the best-practice firm in terms of TFP change belonged to the private sector, while the laggard firm belongs to the state-owned public business sector. In addition, no differences of significance existed between the performance of private sector and state-owned generics companies. Additionally, state-owned companies which have been subject to partial privatization did not exhibit higher levels of TFP change compared to those which remained under full state-ownership. Interestingly, and in relationship to a protectionist regulatory regime, empirical results also indicated that mean TFP change for the sample

firms throughout the study period (1.01) exceeded the mean TFP change for all Egyptian industries (0.75), and that there was evident disassociation or week correlation -at best- between productivity growth and the degree of export orientation.

Chapter Six attempted to provide an answer to the research question concerning how far and in what ways have the regulatory framework governing Egypt's generics pharmaceutical industry allowed local companies to charge higher than average relative prices compared to other world markets. Chapter Six commenced by providing a brief review of the literature concerning the nature of competition on the pharmaceutical market, thus setting the scene to address the research question concerning relative prices of pharmaceuticals on the Egyptian market. Empirical evidence concerning relative prices on the Egyptian market for a selected sample of molecules was then presented. Sample molecules were selected on the basis of the methodology followed by the WHO and HAI (2006) concerned with the international comparison of the prices of chronic disease medicines. The examination of price competition on Egypt's pharmaceutical market indicated that generic-to-originator prices in Egypt have been found to be higher than the standard ratios observed in major world markets. Of no less importance, generic diffusion has not necessarily been bringing down average prices on the Egyptian market. Evidence has also been presented that prescribing habits have resulted in a situation whereby the least priced generics were not necessarily the most prescribed.

Chapter Seven attempted to provide an answer to the research question concerned with the nature and scope of impact of strengthening the country's IPRs regime in conformity with the TRIPS Agreement on pharmaceutical price levels in Egypt, as well as the market shares of key players. Chapter Seven probed into the costs associated with enforcing pharmaceutical product patent protection in Egypt as of January-2005, by relying on proprietary data concerning the country's 42 top therapeutic classes from IMS, in order to examine pharmaceutical market dynamics in Egypt during the period 2004-2008. A first step was to identify new products which have not been facing generic competition on Egypt's pharmaceutical market. Results indicated that in 14 of Egypt's top 42 study therapeutic classes (accounting for 50 percent of the retail market by value) as identified

through IMS, there was evidence regarding launches of new molecules by research-based pharmaceutical companies on the Egyptian market, with no evident generic competition. Together these 14 therapeutic classes account for two percent of the Egyptian pharmaceutical market by value, as well as 14 percent of the sample therapeutic classes.

Within the 14 therapeutic classes, which have been impacted on by the TRIPS Agreement, a total of 24 molecules have not been facing generic competition against brand-name products falling within their domain. Between 2004 and 2008, Egyptian consumers paid a total LE 605 million for products falling within the domain of new molecules, which faced no generic competition.

Of the total cost to consumers, some LE 126 million were incurred over products, which are not protected by patents, and yet have no visible generics competitors. These results indicated that the impact of the TRIPS Agreement has so far been relatively modest, compared to the overall market size. Of no less importance, the fact that it is not only patents that disallow generic competition, warranted special attention.

Chapter Seven presented an assessment of the extent to which Egyptian consumers have been willing to trade-off lower prices of older drugs for more innovative new products. Results concerning shifts in market shares between old and new molecules have indicated an important trend regarding consumer preference for new generation molecules within the scope of the country's top 42 therapeutic classes. In 15 out of some 24 molecules in which there has been no evidence of generic competition in Egypt between 2004 and 2008, consumer demand has been gradually shifting in favour of new products introduced. This shift has been occurring despite the fact that relative prices of new products were much higher than older generation molecules already present within the same therapeutic class. Market data has also indicated that between 2004 and 2008, the local private sector has maintained the position of the dominant player in 6 out of the 14 therapeutic classes which saw the introduction of patent-protected products. The same did not hold true for the public business sector, which has been losing share. This loss is, however, not necessarily attributable to the impact of the TRIPS Agreement, but rather to sector specific ownership

related problems, which have not allowed this important segment of the manufacturing sector to invest sufficient resources needed to compete in what is becoming a highly aggressive market.

Chapter Seven also presented survey results which covered 25 of Egypt's key players on the pharmaceutical manufacturing scene -including public business sector companies, local generics manufacturers and subsidiaries of research-based pharmaceutical companies- concerning their forecast regarding the impact of the TRIPS Agreement on their business. The survey was conducted in April 2004, almost one year before the enforcement of the 20-year period of pharmaceutical patent protection in Egypt. By comparing the survey results to actual market dynamics after January 2005, Chapter Seven closed by highlighting that the survey results have indicated that the majority of perceptions regarding the future state of the business following full respect of pharmaceutical product patent protection in Egypt as reflected in the responses of the various players suffered from flaws in judgment.

Chapter Eight presented a review of the research, the summary of findings and policy implications. By 'connecting the dots' concerning the mosaic of findings presented in the different chapters, it argued that the research has contributed to the debate on industrial policy with concrete empirical findings from Egypt's generics pharmaceutical industry.

From an efficiency perspective, and taking efficiency at the manufacturing sector-wide level in Egypt as a bench-mark for comparison, evidence has been provided that an industry can be protected, yet exhibit positive productivity growth as reflected in relatively healthy efficiency levels. While Egypt's generics pharmaceutical industry -based on sample firms- proved to operate at relatively respectable levels of efficiency, it has been highlighted that this sector has been taking advantage of the captive local market, as well as the absence of pharmaceutical product patent protection, to drive up prices beyond standard world generic-to-originator prices as evident in the sample molecules. The consumer, who pays his/her pharmaceutical bill out-of-pocket is the ultimate looser from this protectionist formula. This protectionist formula is even harsher in light of the fact that the national drug policy in Egypt provides no clear guidelines to the private health care sector to either promote

generic prescription, nor to allow generic substitution by the dispensing pharmacists of the least priced generic available.

On the policy front, a key message to be rallied was that to date, public business sector pharmaceutical companies have been bearing the full brunt of acting as the social arm of the state in terms of the provision of artificially low-priced pharmaceuticals in Egypt. This situation has remained unchanged, in spite of reforms targeting the institutional and legislative regimes brought about by the ERSAP as early as 1991. It was repeatedly expressed during interviews conducted with industrialists, as well as in the unpublished literature that by artificially repressing price adjustments in Egypt's public business sector companies, this policy has impacted negatively on the profitability levels of these companies, and hence their ability to invest in technological upgrades, needed to support higher levels of efficiency. One policy option, though a long-term one is, to strengthen the outreach of the social health insurance scheme in terms of coverage of pharmaceutical needs. This option, will grant these public business sector manufacturing entities breathing space to advance in the right direction in terms of being able to revise prices upwards, and hence invest in the needed levels of technological upgrades to allow for sharpening their competitive abilities.

Another important policy message related to the observed levels of export performance, is that for local generics companies to be able to secure acceptable levels of turnover and profitability, exporting will no longer be an option, but will be imperative for survival. The state has an important role to play, by creating the right incentive framework for these companies to export and by supporting the efforts of local companies to overcome regulatory hurdles in export markets.

On the price competition front, while local companies have been complaining of the rigidity of the pricing system, it was evident, that generic products need a new pricing formula to ensure that prices align with standard world generics-to-originator ratios. The need for a clear generics substitution policy in Egypt should also be high on policy makers' agenda.

Chapter Eight also presented a final policy-related message related to evidence concerning the impact of the TRIPS Agreement in terms of increased relative prices of new products, which have not been facing generics competition. While the price related impact has remained relatively modest compared to the overall market value, the price impact is gradually building up in terms of possibly adding hardship on the uninsured masses, and a safety net, which is to support low-income consumers need to be structured as early as possible.

2. LITERATURE REVIEW AND CONCEPTUAL FRAMEWORK: THE EVOLUTION OF THINKING ABOUT INDUSTRIAL POLICY AND PRODUCTIVITY

2.1 Introduction

This thesis has been motivated by the debate concerning industrial policy, and the nature of outcomes of the various policy options decided on by governments in their quest to achieve industrial development and diversification.

To date, and within the confines of the large body of development literature, the debate concerning the nature and scope of government involvement in economic activity has been among the longest standing. In this chapter, I present a review of the literature on one important facet of government intervention in the economy, namely industrial policy. The key objective of this review is to eventually be able to contribute to this debate, with concrete empirical evidence presented through examining the performance of Egypt's generics pharmaceutical industry. Egypt's generic pharmaceutical industry provided an interesting case study with relevance to the debate on industrial policy, because of the fact that this sector of manufacturing activity continues to thrive behind protectionist non-tariff regulatory trade barriers, which have consistently sheltered local companies from import competition, in spite of several episodes of trade liberalization during the study period. What renders the case study of Egypt's generics pharmaceutical industry even more important in relation to the debate concerning industrial policy was the fact that if there was to be a cost associated with protectionism, then this cost is eventually shouldered by what can be called 'patients' rather than 'consumers'. In Egypt, some 68 percent of pharmaceutical expenditure is made out-of-pocket (Partners for Health ReformPlus, 2005). The fact that 22 percent of Egypt's population are categorized as poor, and another 6 percent as ultra-poor (Egypt Human Development Report, 2010), renders this case study even more meaningful to the debate concerning industrial policy.

The literature on industrial policy embraces a wide continuum of policy options, with free trade and protectionism falling on its extreme poles. Various incentives which solicit certain outcomes, also fall on this wide continuum. How and why have the policy choices

made by governments differentially elevated some of the developing nations to the status of NICs, while others have lagged behind, is perhaps the most important of insights to be derived from this body of literature.

It is being argued that in the domain of Egypt's generics pharmaceutical industry, industrial policy has consistently fell short of embracing the hybrid mix of industrial policies behind the economic success of the NICs, particularly in terms of instigating rapid industrial growth and diversification. In the NICs, governments intervened to support the transfer of technology as well as the development of indigenous technological capabilities. While governments have been aggressively picking and creating winners at the industry and firm levels through interventionist policies, infant industries were more often than not awarded protection in conjunction with export targets. This policy-mix enticed industries to become competitive on world markets, thus sharpening their ability to sustain competition locally once liberalisation becomes part of the policy equation. The selectivity element of the industrial policy model followed by the NICs, has been primarily guided by the principle of efficiency and not any other motive.

In this chapter I also cover the concept of efficiency, which has been at the heart of the debate concerning industrial policy. The underlying reasons behind differential efficiency/productivity outcomes among various countries/ industries/ firms are being presented. The conceptual framework of the thesis, therefore, rests on the notion of efficiency as comprehended in a manufacturing setting.

This chapter is divided as follows. Section 2.2 presents an overview of the key perspectives on industrialisation as appearing in the literature. Section 2.3 presents the conceptual framework. Section 2.4 summarizes the relevance of the literature review and conceptual framework presented to the research questions.

2.2 Perspectives on Industrialisation, the Viewpoints of Competing Paradigms

A starting point for the review of industrial development models was provided by the Bretton Woods Conference which was held in 1944, and which presented an important

point of departure for competing industrialisation paradigms following the end of World War Two.

Free trade and the institutional foundation of the neoclassical school

What the Bretton Woods Conference succeeded in, was to basically put in place the institutional foundations of neoclassical economic thought, which embraced the principles of a liberal international economic order (Bhagawati, 1984: 1-2).

The main thesis of the neoclassical school was to basically allow free price mechanisms to rule with minimal involvement of governments in the economy, particularly with regards the productive sectors. Of no less importance has been the supremacy of the rules of comparative advantage in dictating specialisation in either the production of primary products versus industrial products, and as well as within various sub-sectors of industrial activity. The proper role of government, as viewed by the neoclassical paradigm, was not to go beyond its "lump-sum transfers of taxes and subsidies", with market forces relied on to provide the efficient mechanism to set resource allocation.

Any intervention by the state was seen as distortionary and was *religiously* advised against, particularly in the area of trade. A nation which resorts to the use of either tariffs or subsidies (protection or promotion) to create a wedge between market prices and social costs, rather than to close this gap, was regarded to challenge the efficient world allocation of resources. Free trade was regarded as the equally beneficial and binding policy from the perspective of both developed and developing counties (Bhagawati, 1985: 34).

Chang (2002) pointed out through the critical review of the early industrialisation strategies and policies adopted by a group of the 'now' developed countries that "the policies that were used are almost the opposite of what the present day orthodoxy says". England, the United States, Germany, Sweden and the Netherlands, have themselves endorsed policies of infant industry promotion, and have deployed heavily protectionist trade policies during their early years of industrialisation.

The following section presents the case made in support of infant industry protection, which ultimately led to the rise of import substitution industrialisation (ISI) as known in its contemporary application.

The theoretical case for industrial protection: the infant industry argument

A debatable issue is whether trade policy determines industrial policy or whether the opposite is true. Viewing policy sequence from a Ricardain perspective reveals that under a free trade regime, industrial specialisation is dictated by a country's comparative advantage, with trade policy basically determining industrial policy. List (1856) however, turned this notion upside down, having argued that a nation should 'decide' what it wants to manufacture and then structure its trade regime accordingly. List promoted what became known as the 'infant industry' argument, which laid the first analytical argument for industrial protection as we know it in the modern sense. List explained that a system of protection would not give rise to monopoly, but regarded it as a 'reward' to those who risk their capital and talent to the advancement of industrialisation. The notion of protection as advanced by List was based on the objective of capturing future gains by means of 'present sacrifice' (List, 1856: 224).

While List provided significant intellectual and practical inspiration to the industrialization efforts of countries wishing to challenge the supremacy of British industrial hegemony during the late eighteenth century, particularly the United States where he lived in exile, ISI as applied during the 1950s and 1960s drew much of its theoretical foundation from the works of Hans Singer and Raul Prebisch. The Prebisch-Singer Thesis provided evidence regarding the secular decline in the terms of trade of industrial versus primary commodities, and the subsequent loses of income gains from trade. Evidence regarding the secular decline in the terms of trade was translated into policy action through ISI, which as a policy was supported by an array of tariff as well as non-tariff barriers to shield the newly established industrial entities.

The market failure approach to modern welfare economics also challenged the neoclassical orthodoxy by pointing to the evident failure of the market mechanism in equating private

and social costs and benefits and with the possible correctives of such failures through state intervention (Chang, 1994). Discussions of market failure have traditionally focused on externalities, natural monopolies and public goods, as well as issues of incomplete markets, the pervasiveness of imperfect competition and information failures, moral hazard, adverse selection, and the inequalities of market outcomes (Stiglitz, 1988: 1991).

ISI provoked considerable controversy due to the theoretical and policy challenge pushed against the neoclassical paradigm regarding the merits of free and uninterrupted mechanism of the market. Any "deliberate active economic policy designed to influence the amount and composition of investment could not, according to this school, raise national income in the long run" (Rosenstein-Rodan, 1943: 204-7).

The tools of industrial policy, the viewpoint of the competing paradigms

Having set the basic difference to understanding how industrial development was to be attained from the perspective of the two main competing paradigms which emerged after World War Two, it follows that such differences in the perception of the context as well as the route to development were reflected in the policy tools which were put into actual practice by countries subscribing to either of the viewpoints. It is important to mention that regardless of which side of the fence is being examined, every nation in the world, regardless of its ideological and economic orientation, exercised some form of industrial policy.

On the neoclassical side, however, whenever the debate regarding the merits of industrial policy is opened, a defensive attitude follows, simply because "both terms in 'industrial policy' are suspect" (Wildavsky, 1984: 24). Calls to "get the government off the back of the private sector" do not take into account that whether the private sector likes it or not, governments have been and will remain to be influential players in the global competitiveness game (Johnson, 1984:7).

Industrial policy provokes little, if no controversy, if conceptualised in its broadest perspective as understood under a neoclassical framework. Such a broad definition views

industrial policy to be restricted to providing adequate infrastructure, a limit on the power of monopolies and cartels, indicative guidance regarding future industrial prospects (but without either compulsion or subsidies) a stable and simple tax structure, a free and flexible capital market and a progressive move towards zero sectoral protection (Corden, 1980). Along the same lines, non-controversial definitions of industrial policy view it to embrace "all government actions which affect industry: its domestic and foreign investment, foreign trade, regional location, innovation activities, labour absorption, access to capital markets and environmental use" (Donges, 1980: 1989). Key components of industrial policy are seen to be centred on promoting long-run economic growth, productivity as well as avoiding/eliminating structural rigidities, which are likely to impede change, with the best industrial policy being one which gradually ensures its own disappearance (Johnson, 1984; Corden, 1980).

The tools of industrial policy as practiced in developing countries have been markedly different from the above. Selectivity, coupled with the targeting of industries 'strategically' posited to alter static comparative advantage, in favour activities of a higher value added nature, has been central to industrial policy as practiced in most developing countries under ISI. Protective and sometimes prohibitive tariffs and quotas as well as subsidies were the prime policy tools used to advance ISI.

Industrial policy in a developing country context was also assigned the responsibility of initiating and co-ordinating government activities with the aim of leveraging upward particular industries. Industrial policy in this sense was understood to target the preservation of employment in a particular sector or region (defensive), as well as taking the form of adjustment measures designed to improve the efficiency of particular industries (positive adjustment) (Corden, 1980). Industrial policy was, in a sense "a summary term for government activities that are intended to develop or retrench various industries in a national economy in order to maintain global competitiveness" (Johnson, 1984: 7).

While the case for infant industry protection is difficult to refute as long as a time element is tightly integrated in it, more often than not, protected industries do not grow out of their

infancy stage, with subsidies (promotion) as well as tariffs (protection) giving rise to rent seeking activities, which otherwise would have not occurred in their absence. In addition "while these changes are supposed to permit productivity to increase more rapidly in protected infant industries of LDCs than in the developed countries, the evidence suggests that protection has rather retarded productivity growth… tends to discourage exports as production in the confines of domestic markets limits the exploitation of economies of scale, capacity utilisation and technological improvements" (Corden, 1985).

The ascendancy of neoliberalism

Several factors led to the disenchantment with ISI, thus paving the way for the neoliberal school of thought -the theoretical extension of the neoclassical paradigm- to emerge as the dominant economic paradigm, particularly after the looming of the debt crisis of the early 1980s. Because most of import substituting industries was to varying degrees dependent on imports of either capital goods and/or intermediates, shortages in foreign exchange undermined the sustainability of this policy, particularly for excessively inward oriented industrial sectors. External shocks triggered by oil prices, exposed the vulnerability of ISI, thus ushering the demise of this model, which initially brought rapid growth, diversification and growing per capita income. Palma (2003) attributed the failure of ISI as implemented in Latin America to the dogmatic application, which excluded parallel export promotion.

Comparing the strategies followed by the first tier of NICs Taiwan, Singapore, South Korea and Hong Kong, to Latin America revealed that "on the tariff front, the NICs used protection at levels often higher than those of Latin America, but the crucial difference was that huge effective protection -and cheap finance- was only granted if producers were able to fulfil specific export targets. In this respect, ISI and export-led growth were never mutually exclusive alternatives for the NICs: ISI was simply the platform and source of finance (due to 'over-pricing' a captive market) for their export drive. In turn, export orientation forced levels of investment, productivity and product quality that a purely inward-oriented ISI could never deliver" (Palama, 2003: 136-137).

Disenchantment with ISI seemed to vindicate the much earlier concern of J.S. Mill who cautioned in his 'Principles of Political Economy' that ".. it is essential that the protection should be confined to cases in which there is ground of assurance that the industry which it fosters will after a time be able to dispense with it" (Mill,1998). In other words, targeting did not mean the "promotion of technologies that are unlikely to develop at all on their own; it means, rather helping them rapidly to achieve the necessary economies of scale and manufacturing efficiency without which they can never become internationally competitive" (Johnson, 1984: 10). In fact this was the original essence of ISI as preached by Prebisch in the 1950s, who was initially concerned with the limits of ISI and was rather keen on the development of a free trade area in Latin America to allow for the development of a range of complementary light industries on a continent wide basis (Toye, 2003). This seems to have been 'the' critical missing ingredient which brought about the demise of ISI as a development strategy.

Neoliberalism was fiercely replacing the Stucturalist approach to development, applying modern versions of the dominant economic doctrine of the late nineteenth and early twentieth century. Neoliberalism saw in the early twentieth century the golden age of capitalism, during which state ownership and regulations of industry and finance were absent, labour markets were flexible, strong anti-inflationary macroeconomic policies as well as the free international flows of capital and trade were binding. To emulate this golden age, the neoliberals advocated reform programs, which were basically made-up of privatisation, radical deregulation, liberalisation of the goods and capital markets and the adoption of tight macroeconomic policy (Chang, 2003). These policy items were featured in almost all stabilisation, economic reform and structural adjustment programs which were the standard policies advised by the Bretton Woods institutions, namely the World Bank, the IMF and more so on the trade front by the WTO, particularly after 1995. The TRIPS Agreement complemented what came to be known as the 'Washington Consensus', by breathing life into one of the previously neglected facets of the neoliberal paradigm, namely the developmental role of IPRs. Such a role was linked to the positive impact on the global harmonisation of IPRS on bringing the much-needed role of foreign direct investment (FDI) into the development equation (Mansfield, 1994).

Comparisons between the dogmatic application of ISI (in Latin America and other parts of the developing world including Egypt) relative to the more pragmatic industrial strategies adopted by the first tier of NICs stirred a massive policy debate as to whether industrial policies applied in this highly successful part of the developing world were the triumphant victory of the neoliberal paradigm in delivering 'development' versus a unique model of a 'developmental' state which increasingly used a hybrid of policy tools that in no evident way relied on exclusive market forces to achieve the development 'miracle' of East Asia.

The East Asian model of industrial development

Like success, which has many fathers, the East Asian Miracle was claimed to reflect the ethos of several competing paradigms. Bhagawati (1985) one of the most ardent supporters of free trade, saw in the experiences of the NICs a "superlative economic performance of those countries in particular the four tigers of East Asia that unilaterally liberalised their trade regimes during the 1950s". Among the series of studies to follow this approach was the World Bank (1993) report of the East Asian miracle, with the suggestive title of 'Economic Growth and Public Policy' arguing that the high growth success of the NICs was in large measures achieved by 'getting the basics right'. From the perspective of the Bank, private domestic investment and rapid and growing human capital were the principal engines of growth. Macroeconomic performance was stable and macroeconomic management prudent. Against mounting evidence that targeting and intervention were characteristics of the NICs developmental model, the Report acknowledged that "in most of these economies, in one form or another, the government intervened -to foster development and in some cases the development of specific industries. Policy interventions took many forms; targeting and subsidizing credit to selected industries, keeping deposit rates low and maintaining ceilings on borrowing rates to increase profits and retained earnings, protecting domestic and import substitutes, subsidizing declining industries, making public investments in applied research, establishing firm and industry-specific export targets, developing export marketing institutions…" (World Bank, 1993: 5).

While most, if not all of these policies, did violate the dictum of the neoclassical paradigm, the Report was strictly adherent to the conclusion that:

> "Despite these actions…very little evidence that industrial policies have affected either the sectoral structure of industry or rates of productivity change..industrial structures in Japan, Korea and Taiwan China, have evolved during the past thirty years as we would expect given factor-based comparative advantage and changing factor endowments. It is not altogether surprising that industrial policy in Japan, Korean and Taiwan China produced mainly market-confirming results. While these governments selectively promoted capital and knowledge intensive industries, they also took steps to ensure that they were fostering profitable, internationally competitive firms…Moreover, their industrial policies incorporated a large amount of market information and used performance, usually export performance as a yardstick" (World Bank, 1993: 21-22).

The policy message relied from the Report is that "the promotion of specific industries generally did not work and therefore holds little promise for other developing counties.. Export-push strategies have been by far the most successful combination of fundamentals and policy interventions and hold the most promise for other developing economies". This statement summarised the policy advice of the neoliberal paradigm.

The challenge to the claim that the East Asian miracle was a neoliberal success story, came well ahead of publishing the World Bank Report. Wade (1990) presented a 'governed market' (GM) theory to the interpretation of the NICs success story, building on the foundations of the older vintage of development economics, as well as the concept of the 'developmental state' theory of East Asian industrial success. The GM theory argued that the superiority of the East Asian economic performance was due to the combination of high levels of productive investment, which allowed for the rapid transfer and deployment of newer technologies into actual production as well as investment in key industries that would have otherwise not occurred in the absence of government intervention. The exposure of many industries to international competition in foreign export markets meant that efficiency and cost competitiveness were key to success. At a second level of causation, the government was successful in guiding/governing the market process of

resource allocation so as to produce different production, and investment outcomes than would have occurred under either free or simulated market policies. These included a mixture of incentives, controls as well as mechanisms to spread risk. At a third level of explanation, the organisation of the state structure and the symbiotic relationship with the private sector has allowed for the successful implementation of such policies (Wade, 1990: 26-27). Of no less importance in Wade's GM theory was the emphasis on the development virtues of a hard or soft authoritarian state in corporatist relations with the private sector. The centralised bureaucracy of such a state retained enough autonomy needed to influence resource allocation in line with long-term nationalist interest, which may sometimes come in conflict with short-run profit maximisation (Wade, 1990: 29).

There was a consensus that the economic success of the NICs group of countries particularly in terms of industrial growth demonstrated how "active government intervention" (Stiglitz, 1996: 151) was conducive to the transfer of technology as well as the development of indigenous technological capabilities (Evans, 1995; Thurow, 1993). The interpretation of the East Asian experience provided evidence that governments were aggressively picking or creating winners at the industry and firm levels by intervening in trade, credit allocation, technology imports and local technology diffusion and creation, and in the area of education and training as well as export activity (UNIDO, 1994: 5).

Empirical evidence regarding the success of interventionist policies provided by the East Asian NICs gave added support to List's original infant industry argument but from a different perspective. Infant industries were only awarded protection in conjunction with export performance, which enticed them to become competitive on world markets and thus more able to sustain competition locally once liberalisation figures into the equation. Thus, while specific industries were targeted, the final aim was to improve the efficiency of the economy as a whole. In many cases, "in an 'industrial policy regime' if the efficiency objective of an industry is in conflict with that of the economy in general, that of the economy as a whole should be permitted to dominate" (Chang, 1994). The policy message was that the selectivity or targeting element of industrial policy should not conceal the fact

that its guiding principle should be efficiency and not other motives such as equity for example (Chang, 1994).

The key objective of the above exposé was to pave the way for interpreting the results concerning the efficiency level exhibited by Egypt's generics pharmaceutical industry during the study period against the competing paradigms regarding the outcome of protectionist policies in the domain of manufacturing activities. Whether or not the outcome of protectionism has been manifested in retarding productivity growth in the generics pharmaceutical industry rather than supporting it, is the key concern of the following chapters, which provide the empirical evidence to contribute back to this important debate.

The following section presents the conceptual framework of the thesis.

2.3 Conceptual Framework

Conceptually, productivity measures the efficiency with which resources (including capital and labour) are employed in production (Klein, 1983: 4561). The concept of technical efficiency dates back to the work of Debreu (1951) and Koopmans (1951), when both scholars addressed the issue of efficiency in the economics literature. Farrel (1957) then followed by building on earlier work to introduce the notion of efficiency measurement.

Firm-level efficiency essentially consists of two main components. The first is technical efficiency, which deals with the ability of a particular firm to obtain maximal output from a given set of inputs. The second is allocative (price) efficiency, which indicates the ability of firms to use inputs in optimal proportions. Combining these two measures provides a measure of total economic efficiency (Haghiri et al., 2004). Technical efficiency is defined as a comparison between the observed and maximum values of a particular firm's inputs and outputs. Comparisons can embody the form of the ratio of observed to maximum potential output obtainable from given input (input-oriented measure), or the ratio of minimum potential to observed input required to produce the given output (output-oriented measure), or some combination of both (Haghiri et al., 2004).

Central to the measurement of productivity is total factor productivity (TFP). TFP measures the economic as well as the technical efficiency with which resources are transformed into products. TFP is the portion of output not explained by the amount of inputs used in the production process. Levels of TFP are thus determined by how efficiently and intensely the inputs are utilized in the production process (Comin, 2006). TFP growth has assumed central importance in the economics literature because of the fact that the growth of an economy, an industry or a firm is determined by the rate of expansion of its productive resources and the ratio of TFP growth (Nishimizu and Robinson, 1984: 180).

TFP growth essentially plays a pivotal role in economic growth, as well as cross-country per capita income differences. Solow (1956) has shown that the long-run growth in per capita income in an economy (with aggregate neoclassical production function) must be driven by growth in TFP. Achieving rapid and sustainable positive rates of TFP growth, has thus become a prime objective for policy makers, particularly in a developing country context.

Looking into why there have been differential productivity outcomes among various countries/ industries/ firms, the literature has indicated that this may actually arise from a plethora of sources. Trends in TFP may mirror the efficiency of a particular reform program, learning effects, the deployment of new generations of technology, technical know-how, organizational skills, enterprise response to changes in competition -which is a central issue of this thesis- and other related aspects of market structure. In addition, TFP trends may also reflect the impact of social, political and institutional obstacles to potentially useful innovations. Nonetheless, it has remained difficult to ascertain the causes of productivity movements (Jefferson, Rawski and Zhend, 1996: 147).

Two issues in relation to TFP growth are particularly important and relevant from a development policy perspective. The first issue is related to the range of TFP growth rates that one can be 'reasonably' expected. This can be addressed by looking at confidence intervals for TFP growth rates which can be obtained from historical records of firms,

industries or economies operating under various production and regulatory settings. For example, these observations provide significant insights in relation to an appropriate duration of infant industry protection. The second issue of policy relevance is related to the cause and source of TFP growth. In this regards, it has become important to both question as well as to find answers as to whether or not protection from import competition blunts the incentives for efficiency improvements (Nishimizu and Robinson, 1984: 180). It is this type of questions which is clearly central for this thesis.

Researchers as well as policy makers have been interested in factors which underlie observations that some countries are more productive than others, some industries are more productive than others and some firms are more productive than others. Factors which proved to be important included ownership, the quality of labour, technology used, exposure to competition in export markets and the regulatory environment (Bartelsman and Doms, 2000: 586). In close connection, among the central issues invoked in the literature on productivity is related to the extent to which exposure to foreign markets relates to producers' choice and productivity dispersion within a particular industry. In fact, plant level exporting has gained significant attention, and has been motivated by evidence of a strong relationship between exporting and productivity growth (Bernard and Jensen, 1995).

Researchers have extensively embarked on examining the underlying reasons behind observed productivity levels and growth rates in various nations, industries as well as firms. The objective has generally been to evaluate their mutual competitive positions, particularly with regards international trade. On this front, of significant policy relevance has been the contention that countries that have exhibited strong productivity growth, have also been highly competitive internationally (Klein, 1983: 4565).

Research regarding productivity served to answer a rich plethora of questions, which have in turn been tackled by using a narrow set of measurement techniques as will be elaborate on further.

On one hand, a large body of literature has looked into the relative productivity of locally owned firms versus foreign owned firms, with the objective of formulating more effective policies with regards FDI. Along such lines, Asheghian (1982) attempted to evaluate the comparative efficiency of foreign firms and local firms in Iran in an effort to present intra-firm efficiency comparisons (based on three indices of efficiency including TFP). The study concluded that international joint-venture firms (as opposed to wholly owned subsidiaries) which have been operating in Iran during the pre-revolutionary period 1971-76 have been more efficient than locally owned firms. Chung et al (2003) focused on the influence of Japanese FDI on the productivity of US suppliers in the US auto-component industry during a study period which extended between 1979 and 1991. This study was based on observing linkages between various firms supplying auto-components to Japanese transplants, as well as the productivity and survival of the US component firms that did not supply Japanese transplants. The authors found out that the productivity of local suppliers with linkages to Japanese transplants did not grow faster than that of unaffiliated suppliers, and concluded that there was no evidence of direct technology transfer positively affecting US suppliers' productivity during the study period (which was coined as the initial stage of inward FDI in the USA).

Among the interesting segments of research work on productivity, is the body of literature linking exporting to productivity growth. Exporting is regarded to positively contribute to productivity growth through three key channels: 1) economies of scale; 2) efficiency improvements on behalf of exporters though the process of 'learning by exporting', cross-efficiency promotion and resource reallocation from the less to the more efficient firms at the industry level and 3) technical progress which result from technology spill-overs through foreign contracts and the encouragement of investment in research and development (Fu, 2005; Bartelsman and Domes, 2000).

Empirical research examining whether or not export-oriented firms exhibit higher levels of productivity than non-exporting firms has produced mixed results. One faction of the literature has argued that there is a process of 'learning-by-exporting' whereby exporting firms serve as a conduit for technology transfer from abroad and do generate technological

spill-overs to the rest of firms operating in their domain of operations. Another faction states that the relatively high productivity of exporting firms reflects the mere fact that it is the relatively more efficient producers who do enter and sustain presence in the highly competitive export markets. This reflects a 'self-selection' process which works in the export industries (Fu, 2005).

On one side, research based on examining microdata in developing countries has shown that exporting firms are generally more efficient than non-exporting firms. The study by Clerides et al. (1998) confirms this pattern and adds the interesting finding that plants that cease to export typically become less efficient. Taking a step further in the analysis by looking into causation flows from exporting to productivity improvements, data from Colombia and Morocco pertaining to export-oriented industries was found to be inconsistent with this pattern of causality (Clerides et al., 1998). Fu (2005) also investigated the relationship between exports and industry-wide productivity growth in China's manufacturing sector. By relying on industry-level panel data for the period 1990-97 (using a non-parametric Malmquist TFP approach), the author found out that export-oriented industries did not appear to have been more efficient than non-export industries. No productivity gains of significance have been caused by exports at the industry level (Fu, 2005).

In contrast to this kind of observations, basing their empirical work on data from the Penn World Tables for 102 countries, and using measures of 'real' openness (defined as imports plus exports in US Dollars exchange rate relative to GDP in purchasing power parity US Dollars) Alcala and Ciccone (2004) have found that the causal effect of trade on productivity is statistically significant as well as robust. This finding has indicated that the channels through which international trade impacts on average -labour- productivity is through TFP. Handoussa, Nishimizu and Page (1986) have also provided evidence from Egypt's state-owned companies in the manufacturing sector after the ODP, whereby exporting firms were found to be relatively more efficient than their inward-oriented counterparts.

Clerides et al. (1998) also posed the interesting question of whether firms become more efficient *after* becoming exporters. The authors track the causal link from exporting to productivity growth using plant-level panel data. They also looked into whether the cost process of individual firms undergoes change after they move into export markets. The results indicate that the relatively more efficient firms become exporters. However, firms' costs are not significantly affected by previous exporting activities. The positive association between exporting and efficiency gains documented in the literature is, nonetheless, explained by the *self-selection* of the more efficient firms into export markets (Clerides et al, 1998). In close connection, Pavcnik (2002) addressed the more boarder issue of trade liberalization and productivity growth using panel data for the 1979-86 period for all manufacturing plants in Chile employing ten or more workers. The author found that there was significant support for productivity improvements related to liberalized trade. Following trade liberalization during the late 1970s and early 1980s, the productivity of plants in the import competing sectors grew by an average of 3-10 percent more than in the non-traded-goods sector in Chile.

Another important and interesting dimension of research on productivity, is that related to the nature of ownership of productive units. Hauner (2005) looked into the comparative efficiency performance of large German and Austrian banks, state-owned banks were found to be more cost-efficient (owing to their access to cheaper funds), while cooperative banks were found to be about as cost-efficient as private banks. The study also found out that Austrian banks were significantly less cost-efficient than German banks. In another attempt to link observed patterns of efficiency to ownership, Liu (2001) investigated the effect of state ownership on efficiency (using an econometric model which allowed for the separation of technical from allocative efficiency in a dynamic setting). Basing the estimation results on a sample of international airlines, the author suggested that state-ownership is associated with lower technical and allocative efficiency.

2.4 Summary and Conclusion

In the first part of this chapter, I provided a review of literature on industrial policy, as well as the outcomes of such policy choices during different historical intervals in various parts

of the world. It is safe to argue that the empirical evidence concerning the outcome of industrial policy choices has fueled rather than resolved the debate concerning what an optimal industrial policy should be.

While the neoclassical paradigm, which propagated minimal involvement of governments in economic activity and the supremacy of the rules of comparative advantage in dictating specialization has dominated during the aftermath of World War Two, the Prebisch-Singer Thesis regarding the secular decline in the terms of trade of industrial versus primary commodities has elevated import-substitution-industrialization as the preferred policy option by the majority of developing nations, particularly during the 1950s and 1960s.

The infant industry argument has heavily influenced industrial policy in most -if not all- developing nations. Governments chose to erect tariff barriers to shield their nascent industries against import competition, with the objective of altering static comparative advantage in the production and trade of primary commodities. During the debt crisis of the late 1980s, neoliberalism challenged the basic foundations of the import-substitution paradigm, by providing mounting evidence that protection has retarded productivity growth rather than supported it. Evidence has been provided from Latin American countries, that the total exclusion of export promotion strategies made them vulnerable to external shocks triggered by rising oil prices, while their protected manufacturing industries were not able to capture any shares of significance on export markets or withstand competition on local markets.

The review of the literature also provided the interesting case of the first tier of NICs, that enriched the literature on industrial policy with a new model which blended import-substitution with export promotion strategies. Policy interventions in the NICs provided subsidized credit to selected industries, protected domestic and import substitutes and made public investments in applied research on condition that firms met industry-specific export targets. In this respect, import-substitution-industrialization and export-led growth were never mutually exclusive options for industrialization for the NICs.

The rich set of country experiences, documenting the outcomes of various industrial policies, has nonetheless not finally resolved the debate concerning what an optimal industrial policy should be. By examining the growth trajectory and key performance attributes of Egypt's generics pharmaceutical industry against the literature on industrial policy as well as against the concept of efficiency, I should be able to contribute to this debate with a set of empirical evidence.

By presenting the conceptual framework of the thesis, this chapter also threw light on the concept of productivity and its measurement through estimating TFP, which will be employed in Chapter Five.

3. MAPPING THE GROWTH TRAJECTORY OF EGYPT'S GENERICS PHARMACEUTICAL INDUSTRY AGAINST GLOBAL PATTERNS OF PRODUCTION AND TRADE

3.1 Introduction

In Chapter Two, it has been presented through the review of the literature on industrial policy, that governments intervene to influence outcomes in the domain of industrial activities through a host of polices and regulatory measures. The nature of how do industries perform under the auspices of a protectionist or a liberal regime, has been a long standing question evoked by the literature on industrial policy.

In this chapter, I will examine the growth trajectory of Egypt's generics pharmaceutical industry against the nature of the industrial policy regime(s) which ruled during the study period. The key objective is to provide the background against which the research question concerning the extent to which mechanisms used to regulate and protect the Egyptian generics pharmaceutical industry have been associated with productivity growth will be addressed.

On the basis of the evidence presented in this chapter, it is safe to argue that since its formative years, and passing through different policy and regulatory regimes, the focus as well as the key criteria for success for the Egyptian generics pharmaceutical industry, has primarily been on increasing the levels of self-sufficiency, in what has been regarded as a strategic sector. The various shifts in economic policy direction, as well as episodes of institutional and regulatory reforms have consistently defaulted in shifting the relatively excessive inward orientation of this industry. Unlike the majority of manufacturing industries in Egypt, which have seen protective tariff as well as non-tariff trade barriers being systemically brought down during various intervals, the perseverance of non-tariff regulatory barriers shielding the generics pharmaceutical industry in Egypt has practically isolated this industry from import competition.

This chapter also documents the failure to transcend the boundaries of engaging in sheer pharmaceutical formulation activities and venturing towards expanding research and

development (R&D) capabilities by the local generics pharmaceutical industry in Egypt. Evidence also indicates that Egypt's generics pharmaceutical industry has not been a key contributor to job creation in what is predominately a labor surplus economy. The key achievement of this industry has been manifested in its ability to close down on the levels of self-sufficiency. The important research question which then persists becomes related to whether this achievement has been attained in an efficient manner.

Chapter Three is structured as follows. Section 3.2 presented the salient characteristics of the pharmaceutical industry, with the objective of highlighting the key differences between research-based and generics pharmaceutical manufacturers. It is against this background section that details how similar as well as dissimilar pharmaceutical manufacturers operate on the world production and trade scenes, that the growth trajectory and performance of Egypt's generics pharmaceutical sector will be examined and assessed. Section 3.2 highlighted the fact that while generics companies in some countries such as India have continued to focus on the production of multiple-source generics for the home market, they have also managed to become key players on the global market. This contrasts markedly with the case of Egypt, in which generics companies remain confined to the local market. Section 3.3 evaluated the growth trajectory of the Egyptian pharmaceutical industry against the key objectives of the industrial policy regime(s) which governed during the study period. Sections 3.4 and 3.5 presented the key players on Egypt's manufacturing scene and their market structure respectively. Section 3.6 presented the key performance attributes of this sector in terms of output growth, employment creation, trade performance and R&D activities. Section 3.7 presents the summary of key findings concerning the extent to which the reform program of the early 1990s, as well as the ruling pharmaceutical regulatory framework have been effective in inducing the desired performance attributes expected from this industry along lines the norms observed internationally. Section 3.7 also presented the concluding remarks which identify the key limitations of the ruling policy regime in terms of supporting the generics pharmaceutical industry meet the challenges of its current stage of development.

3.2 Salient Characteristics of the Pharmaceutical Industry

In this thesis, the pharmaceutical industry is defined as one which is concerned with the manufacturing of basic pharmaceutical products and pharmaceutical preparations. This definition is in accordance with the International Standard Industrial Classification (ISIC) Rev. 4 of the United Nations, whereby pharmaceutical products fall under Section C for manufacturing, Division 21.

Measured against a group of indicators such as share in world production, trade as well as profitability, the pharmaceutical industry has emerged as one of the key 'sunrise' industries. The term sunrise describes a range of industrial activities sharing the common denominator of being relatively new, technologically progressive concerns investing heavily in research and development R&D in order to foster not only growth, but more fundamentally, survival given the heightened vulnerability of their products to rapid technological obsolescence. These industries mainly operate in the domain of electronic data processing, electrical and electronic engineering, aerospace and pharmaceuticals (Wells, 1985:11). One of the most obvious features of the pharmaceutical industry is that it is characterised by a very large number of small sellers and a very small number of large companies, which are international in their outlook and competition (Taggart, 1993). The pharmaceutical industry is also by far the most research-intensive of industrial activities. In the USA, which is home to the largest of the research-based companies, pharmaceutical firms invest five more times in R&D relative to their sales, than the average in the manufacturing sector (CBO, 1998). Other characteristics of the pharmaceutical industry which differentiate it from other industries are that the industry has high fixed R&D costs and low marginal costs of production. The industry is also exceptional in terms of the fact that patents rather than first-time mover advantages or any other source of monopoly power provide the key protection from the perspective of innovators (Kremer, 2002).

The pharmaceuticals industry is also characterised by *atypical* attributes, which render supply and demand dynamics of limited insight in understanding how the market for pharmaceuticals functions. In other words normal market discipline simply does not work

(Green, 1997: 1). Demand for pharmaceuticals is dictated by the tripartite division of separate actors, starting with the doctor who prescribes but does not consume the patient who consumes but may not pay and the third party responsible for payment (Cooper, 1966: 114). In fact, a fundamental feature of the health care market is that consumers generally do not choose to pay for the goods they consume (Bloom and Van Reenen, 1998: 323). This feature related to the separation of the authority that prescribes from the responsibility to pay means that in effect "prescribing physicians have little economic motivation to prescribe the lowest-priced brands … patients cannot substitute lower-priced brands for those prescribed by their physicians. As a result, the demand curve for individual drugs or for groups of related drugs are likely to be extremely inelastic" (Jadlow, 1979: 14). This inelasticity is what makes pharmaceuticals "life" and "death" products. Because governments are usually in a monopsonist position, being major buyers of pharmaceuticals -with probably the notable exception of the USA- cost containment efforts have subjected drug prices to extensive regulation (Green, 1997: 1).

The above characteristics are responsible for distinguishing the pharmaceutical industry from all other sectors of manufacturing activity.

3.2.1 A typology of the pharmaceutical industry

The production of pharmaceutical preparations involves the physical production of a drug in its marketed form. This may involve an array of processes such as ingredient compounding and dispersion, granulation and drying, in addition to formulation in the final form (tablets, capsules, etc.). With certain exceptions, such as sterile production facilities, capital costs associated with the manufacturing process tend to be low and techniques are not highly complex, thus allowing companies of almost any size to produce finished pharmaceuticals (James, 1977: 16). Pharmaceutical manufacturers fall in three main categories. These include large integrated corporations, innovative companies and reproductive companies.

Integrated companies

Integrated companies are the large vertically integrated entities capable of engaging in all three stages of drug production, including R&D, manufacturing and distribution. Most of the large drug companies also have their own raw material production facilities. The most important of characteristics shared by the integrated pharmaceutical companies, is the extent to which R&D outlays account for a large (and rising) share of sales. In 2007, the five largest spenders globally on pharmaceutical R&D were Pfizer (USD 8.1 billion), Roche (USD 6.7 billion), Sanofi-Aventis (USD 6.6 billion), Novartis (USD 6.4 billion), and GlaxoSmithKline (GSK) (USD 6.4 billion) (Pharmaceuticals Executive, 2008). Member companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) have seen their R&D expenditure as a percent of sales increasing significantly from 9.3 percent in 1970, to 14.4 percent in 1990 and 16.4 percent in 2007 (PhRMA, 2008).

The operations of integrated pharmaceutical firms are concentrated in a few of the world leading industrial countries. These include the USA, United Kingdom, Switzerland, Germany, Japan, Belgium, Sweden and France. In terms of drug development, the USA leads the league. The share of the USA in the development of some 152 new drugs between 1975-94 stood at 45 percent. The UK followed with a 14-percentage share (Barral, 1995). The USA assumes the same leading position, whereby it accounts for 43 percent out of 6401 compounds currently in the development phase. Europe follows with a share of 22 percent and Japan with 8.5 percent (PhRMA, 2008). It is, therefore, not surprising to find that nine of the world's top 15 research-based pharmaceutical companies are headquartered in the USA.

Countries hosting the world top research-based pharmaceutical companies share the common denominator needed to support the growth of pharmaceutical R&D. Foremost among these requisites are the basic scientific infrastructure in universities, government research institutes and within industry. These are the initial places where scientists are able to gather fundamental new ideas. It is, nonetheless, important to note that it has been industry, rather than academia, which had the resources and expertise to turn basic scientific theories into marketable medicines (Smith, 1985: 67).

Innovative and generics companies

Innovative companies are the second type of companies. These companies distinguish themselves by being able to discover and develop new molecular entities (NMEs), but are typically engaged in the production of patent expired drugs. Their revenue ranges between USD 25-200 million, which does not allow them to fund product development. While they are able to develop NMEs, they often resort to licensing arrangements with larger companies in order to develop and market their products. The third type of companies is the generics manufactures or the imitation-based firms. These firms are often small-to-medium in size, lacking any in-house research capacity, and the drugs they produce are typically off-patent. While the above characterization of firms is not exhaustive, it is sufficient to yield a reasonably accurate typology of the world's pharmaceutical industry (Balance et al, 1992: 1-6).

3.2.2 A Typology of products

Pharmaceutical products are highly differentiated, and therefore, it is difficult to argue that there is 'one' market for pharmaceuticals, whether locally or globally. Pharmaceuticals do not fall in the category of products with large long run cross-elasticities of either supply or demand, to allow for their combination in a single market (Grabowski and Vernon, 1976: 30).

Pharmaceutical products can only be grouped in sub-markets, within which a reasonable degree of substitutability of one product for the other exists. To illustrate with an example, a tranquilliser will have no effect on the sales of an established antibiotic, even though both clearly fall in the category of pharmaceutical products (Cooper, 1966: 59). Distinction is also made between in-patent products, generics and branded generics, as well as between ethical products and over the counter (OTC) drugs. This distinction has significant implications in terms of the cost structure, pricing and competition between products. Competition, therefore, does not take place on an industry wide basis, but should be viewed and evaluated within the domains of particular therapeutic groups of drugs (Grabowski and Vernon, 1976: 32).

In general, the pharmaceutical market is not considered to be highly concentrated. However, when the market is divided into narrowly defined therapeutic classes, high levels of concentration become visible. In the USA, each of the top of brand-name drugs ranked by pharmaceutical sales does not account for more than 7 percent of the entire market for prescription drugs. However, within each of the therapeutic classes, higher levels of concentration are evident. The Congressional Budgetary Office (CBO) of the USA examined 66 of the therapeutic classes on the market, of which in 35, the top three innovator drugs accounted for 80 percent of retail pharmacy sales in their class (CBO, 1998: xi).

Prescription drugs are generally divided into two key categories: innovator drugs and generic drugs. Innovator drugs -also referred to as brand-name drugs- enjoy patent protection on their chemical formulations and are approved following extensive clinical testing under an original new drug application (NDA). Therapeutically similar patented brand-name drugs can exist, though each with a different chemical formulation. Originator drugs which are still under patent protection are called single-source-drugs. Generic drugs obtain regulatory approval under a relatively shorter process than innovator drugs, whereby they rely on the demonstration of "bioequivalence" to an innovator drug. They are, therefore, not patentable (CBO, 1998).

Single-source drugs

Pharmaceutical products which are protected by patents are referred to as single-source drugs. The most important characteristic of single-source drugs is their research-intensity, and hence high fixed R&D cost in relation to total production costs. Research-based pharmaceutical companies diverge from the norm of competitive markets, where prices are based on marginal cost. In light of their high fixed cost and low marginal cost, if innovative pharmaceutical products were to be priced according to their marginal costs, they would be very inexpensive, but on the long run, no R&D activities would be undertaken. The relevant model of price setting allows sellers to act as an oligopoly, whereby prices are set in excess of marginal cost. Higher prices are reinforced by limited competition due to

patent protection, which is not only viewed as a reward to innovation (Schweitzer, 1997: 9), but is increasingly looked upon as an essential means by which a firm could gain funds for future research (James, 1977: 149).

The pharmaceutical industry in particular placed the highest importance on patents in terms of factors which are crucial and necessary to appropriate the benefits from investing in innovation (Grabowski, 2002). Patent protection in the domain of single-source drugs is theoretically regarded to stimulate technical progress in four ways; it encourages invention; it induces the disclosure of discoveries; it makes up for the expenses incurred during the process of developing an invention through commercial rewarding; and it induces the allocation of capital in new lines of production which may not appear profitable if many competitors embark on it simultaneously (Cooper, 1966: 97).

In a single-source drug market, patent protection becomes one of the most significant barriers to entry, along with economies of scale in promotion, product differentiation (based on R&D expenditure) and economies of scale in R&D which require a large minimum scale (Schwartzman, 1976: 305-311). Converting all costs of a cohort of drugs to their present value at the date of their launch, R&D would roughly represent 30 percent of the total cost of production. There is consensus that R&D costs are the most expensive for the pharmaceutical industry. Estimates of R&D costs per NCE brought to the market in the US were put at USD 359 million (Danzon, 1997). Other estimates put the after tax cost per NCE in the range of USD 194 million and USD 241 million. According to PhRMA, the industry requires an average of USD 500 million to introduce a new marketed medicine (Maskus, 2000: 5). In another estimate, the average out-of-pocket cost per new drug was USD 403 million (in 2000 dollars). When capitalising out-of-pocket costs to the point of marketing approval (at a real discount rate of 11 percent), the total pre-approval cost estimate reaches USD 802 million (DiMasi, Hansen and Grabowski, 2003: 151).

Large R&D costs are partially associated with the fact that many failed compounds are investigated for each product that is shown to be safe, effective and patentable. It also takes between 12-15 years (in the USA) for a product to make it from the stage of pre-clinical

research through to clinical testing and regulatory marketing approval to product launch (Maskus, 2000). In fact, most drug candidates actually fail to reach the market, as a result of toxicity, carcinogenicity, manufacturing difficulties and inadequate efficacy. Less than one percent of compounds examined during the pre-clinical period actually make it to the phase of human testing. Some 22 percent of compounds entering clinical trials survive the development process and actually gain regulatory approval. Together, the pre-clinical and clinical testing phases take more than a decade to be completed (Grabowski, 2002).

It is important to mention that most pharmaceutical inventions are covered by a multitude of patents including new uses/indications, dosages and changes in formulations. This typically allows blockbuster drugs to have from 20 to over 40 patents covering the entire range of items (substance, compound, formulation, etc.). The patent system therefore enables patent holders to ensure their products are wrapped well in a series of subsequent protective patents (Lewis, 2001: 10). As such, pharmaceutical companies can build a portfolio of patents around a single product.

It has been repeatedly argued that without patents, the return on investment in pharmaceutical R&D would fall, and there would be no incentive for private companies to engage in R&D. Because the process whereby duplication of drugs can take place in laboratories is fairly easy, patents in the pharmaceutical industry have greater value than for any other of the research-intensive industries (Schwartzman, 1976: 4). Patents grant the innovator a temporal exclusivity right over the innovation as long as the product implies a relevant therapeutic advancement over existing products, and is not just a new chemical compound. Patents under the framework of ruling IPRs regimes can be viewed as a kind of a social contract between society and the innovator, allowing the production of a public good, while the innovator is allowed an otherwise restricted privilege (Rovira, 2002).

Multiple-source drugs

The World Health Organisation (WHO) does not usually use the term ‘generic pharmaceutical products’, usually referring to drugs which are off patent as ‘multiple-source pharmaceuticals’. In the generic or multiple-source drug market, patent protection is

absent, entry barriers are low and products are supplied by several manufacturers, with the market close to a typical textbook case of perfect competition. While the definition of generics does not depend on whether the product is branded or not, there is an agreement that "a product, which is a copy of an original product whose patent has expired, and may be marketed either as a brand or using the generic name fall under the broad category of generics" (Lewis, 2001). Multiple-source drugs may sometimes be marketed in dosage forms and/or strengths which are different from those of the innovator product (Southworth, 1996: 5). Generic drugs only need to show bioequivalence to the originator drug, a process which costs only USD 1-2 million (Grabowski, 2002).

In none of the major world pharmaceutical markets do generics represent more than 30 percent of total market by value, while the volume share may be 40 percent and above. The degree of penetration of branded-multiple source drugs versus generics depends on the specifics of the market in question. In the USA for example, the branded sector is dominant, accounting for 80 percent of the total multiple-source drug market (Southworth, 1996: 8-9). The level of generic substitution varies considerably across therapeutic categories, depending on whether the segments are relatively new. A typical example of relatively new therapeutic categories is anti-retroviral (ARVs). Therapeutic groups which are more mature and contain a multitude of patents that have expired, include the penicillin and antibacterial sub-markets in which generic competition is prolific (Southworth, 1996: 10).

Determinants of generic competition in a certain therapeutic category is dependent on a set of factors including: 1) market size, as the larger the therapeutic category the more likely is the generic interest, 2) number of products going off-patent, 3) the reluctance on the part of either patients or physicians for generic substitution to ensure consistent and steady therapy and 4) the level of substitution may in fact be controlled by the regulatory authorities which may either encourage/reduce generic substitution (Southworth, 1996: 11).

The manufacturing of generics is conducted at minimal research costs, with the cost of production being comprised of product development, manufacturing and marketing. This

means that prices can be set as low as marginal cost. In a single-source drug market, product competition is usually more important than price competition, i.e. the ability to create new medicine is more important than the ability to produce them cheaply.

Once a therapeutic category is open to generic competition, the original patent holder may be forced to reduce prices. The entry of rival products, eventually push the structure of the drug market towards perfect competition (Jadlow, 1979: 14). Using data from the USA, United Kingdom, West Germany and France, Hudson (2000) analysed the consequences of generic competition on the prices of incumbent single-source drugs, and concluded that in the cases of Germany and France, the entry of new generic products significantly reduced the price of incumbent drugs.

Research-based pharmaceutical companies have also been known to establish their own generic subsidiaries. For example, in 1992, Merck established a generic subsidiary 'West Point Pharma', following an internal review of the company, known as Project Paradigm. Project Paradigm concluded that Merck might no longer be able to compete effectively by specializing only on ethical brand-name pharmaceuticals. This strategy has been adopted by several research-based pharmaceutical companies, who also launch generic versions of their own brands before they go off patent. This strategy allows research-based companies to retain market shares and be a step ahead of the generic companies which are unable to launch their own products until after patent expiry (Southworth, 1996: 24).

Increased interest of research based pharmaceutical companies in the manufacturing of generics is explained against the increasing share of generics in the global medicines market. In 1991, the global market for generics was estimated at USD 15 billion, or roughly 8 percent of world market sales (Balance et al., 1992: 12) In 2007, the global generic medicines market (audit and unaudited markets) reached USD 115 billion, which accounts for 16 percent of the world market (EGA, 2007). In some of the world's largest markets, namely the USA, the share of generics has actually been increasing at a significant rate, having accounted for 67 percent of the market in 2007 compared to 51 percent in 2000 (PhRMA, 2008). In Europe, generics account for a lower share of 18 percent in 2005-06,

whereby the generics' medicines market stands at USD 31.1 billion, compared to USD 138.6 billion for the originator market (EGA, 2007).

3.2.3 The process of drug discovery and development

Before scientists decide to focus on a disease area, an analysis of market potential is often conducted, taking into consideration the incidence or prevalence of the condition and the likelihood that the drug, if successfully produced, could be marketed. Once a disease is found to have economic potential, scientists go to work (Schweitzer, 1997: 2).

A NCE is discovered after a long process of synthesizing new chemicals and early pharmacological studies and the attempt to improve the understanding of the physiopathological process. This phase is usually referred to as the "basic research" or the discovery phase. A NCE then enters what is called the development stage (Hansen, 1979). Testes performed during the development stage are short-term animal toxicity tests, in order to predict safety in humans. Only a small percentage of NCEs tested in animal are further judged to be suitable candidates for further development. If the results of the initial animal testing prove to be encouraging, a notice of claimed investigational for a new drug (IND) is submitted to the regulatory authorities. Human or clinical testing then follows in three stages (Hansen, 1979). Details of the three stages are presented in Annex 2. It is actually the clinical testing phase of a new drug which is the most expensive single activity performed (Smith and O'Donnell, 2006: 8). When a company concludes the collection of data from clinical trials, it ends the process by submitting an application to the regulatory bodies for marketing approval. Firms then file the new drug application (NDA) including raw data on all of the tests conducted. For successful candidate firms, the review process by the Food and Drug Administration (FDA) for example usually takes around two years for the approval to be granted (Hansen, 1979: 154). The average time lag from the point of identifying a clinical candidate to approval of a new drug is approximately 10 years (Smith and O'Donnell, 2006: 9).

Whether or not the large size of research-based pharmaceutical companies confers any advantages on an inventor is debatable. The chief ingredients in the innovation process are

imagination and familiarity with frontier scientific advantages. These ingredients in fact come in a non-costly manner. The only advantage large transnational companies (TNC) enjoy is in the development phase of the research process, which is relatively costly because it requires the cooperative efforts of many different specialists. Accordingly, the inventor can dispense of the burden of the development of his invention by selling the patent to a large corporation. The developer does not usually take much technical risk because a research-based pharmaceutical company can recognize a feasible idea. But this does not mean that the process of discovery and development are two completely separate phases. The chemist who synthesizes a compound may be called upon at any phase of the drug life for additional molecular modification, as both the chemist and the associated pharmacologists keep a close watch over compounds late into clinical testing (Schwartzman, 1976: 62-63).

Schumpeter asserted that since modern industrial research requires large resources, large firms would do proportionally more research than small ones, thus producing proportionally more innovations. Three additional reasons for expecting large firms to be more innovative relative to their size include the facts that by undertaking several research projects simultaneously they can reduce their risks. Their diversification also permits them to exploit the unexpected benefits of research and they can achieve economies of scale in research (Schwartzman, 1976: 83).

3.2.4 The cost structure of the pharmaceutical industry

A frequently asked question in the domain of pharmaceutical production is related to the cost structure of the pharmaceutical industry and particularly to the estimation of true R&D costs. Unfortunately, the pharmaceutical industry has often been described as “extremely secretive” as a result the amount of information available on the industry has traditionally been limited (Balance et al, 1992: 3). Nevertheless, one of the most publicized cost components of the research-based pharmaceutical industry is related to R&D.

Discovery phase

What raise the cost of drug production, and thus entry barriers, are the safety and efficacy regulations imposed by governments. Safety and efficacy related costs are concentrated at the development stage rather than the earlier phase of discovery. In fact, potentially significant drugs can be discovered for as little as £ 500,000. It has been often propagated that at the stage of product discovery, it is "brains that count and not money" which means that relatively small companies can play a major role in the early stage of pharmaceutical research (Green, 1997: 5).

Research and development

The development phase is relatively much costly due to regulatory hurdles and the long time lag associated with the process. In Europe, it takes an average of 6-12 years for a product to pass the development phase, with costs varying between £ 100-200 million. It is also important to note that during the screening phase, many products may seem promising, but are later abandoned during the testing phase. A number of independent studies have suggested that only one in 10,000 to 50,000 compounds succeed in reaching the market (Green, 1997:6).

The 1990s, and the new millennium have actually brought major changes in the pharmaceutical industry form the vantage point of R&D as well as commercial operations. New technologies as well as processes such as 'high throughput screening" [3] and "combinatorial chemistry"[4] are currently being widely embraced. The objective of both approaches is to allow for very large numbers of NCEs to be screened for biological activity in vitro. On another front, advances in the fields of genomics and proteomics have

[3] "Using robotics, data processing and control software, liquid handling devices, and sensitive detectors, High-Throughput Screening or HTS allows a researcher to quickly conduct millions of biochemical, genetic or pharmacological tests. Through this process one can rapidly identify active compounds, antibodies or genes which modulate a particular biomolecular pathway. The results of these experiments provide starting points for drug design and for understanding the interaction or role of a particular biochemical process in biology" (http://en.wikipedia.org)

[4] "Combinatorial chemistry involves the rapid synthesis or the computer simulation of a large number of different but structurally related molecules. Synthesis of molecules in a combinatorial fashion can quickly lead to large numbers of molecules." (http://en.wikipedia.org)

made available historically unprecedented numbers of targets with which to search for new drug candidates (Smith and O'Donnel, 2006).

Manufacturing

Manufacturing costs are established to be relatively low in the pharmaceutical industry, as the industry has high fixed costs and low marginal costs. This means that additional costs associated with each additional unit of output is relatively very small. This aspect of pharmaceutical production is very important, as marginal costs determine prices in competitive market as opposed to fixed costs (Schweitzer, 1997: 101).

Because the pharmaceutical industry is comprised of firms of varying sizes and specializations, generalizations about the cost structure are quite difficult. However, in the lead producing countries, manufacturing accounts for about 40 percent of all costs, while marketing absorbs 20-25 percent. Manufacturing therefore emerges as one of the largest costs components. The cost structure is slightly different in developing countries, whereby manufacturing accounts for a much larger portion of total costs, close to well over a half (Balance et al., 1992: 126).

3.2.5 The world pharmaceutical market

In 2010, the world pharmaceutical market has been estimated at USD 856 billion (compared to USD 365 billion in 2000), with North American and European markets accounting for 39 percent and 37 percent of the market respectively (IMS Health, 2011).

Because the cost of launching a new drug is the same regardless of the number of users (Danzon, 1997), the world market is increasingly being tapped. According to the United Nations Conference on Trade and Development (UNCTAD), world trade in pharmaceutical products[5] increased from less than USD 45 billion in 1995 to USD 237 billion in 2006. Roughly speaking, one-half of world production is traded, with the industrialised countries accounting for 94 percent of world trade in pharmaceutical products (UNCTAD, 2008). Trade in pharmaceutical products by developing countries reached USD 10.9 billion in

[5] Figures apply to medicines including veterinary SITC Revision 3, 542.

2003 up from USD 2.1 billion in 1980. Developing countries currently account for 5 percent of global trade in pharmaceuticals (down from 13 percent in 1980). China is the lead exporter of pharmaceutical products among developing countries, accounting for 26 percent of total pharmaceutical exports by developing countries (up from 13 percent in 1980), and 1.4 percent of total world trade. India follows at 1 percent of total world trade (up from 0.7 percent in 1980) and 18.4 percent of exports by developing countries (UNCTAD, 2005).

Global variations in regulatory and IPRs regimes

Global variations in IPRs regimes have given rise to concern by patent and copyright dependent industries regarding profitability levels, which are forgone due to 'pirating' activities by commercial as well as non-commercial entities present in markets with relatively less solid IPRs regimes. During the pre-TRIPS phase, the absence of pharmaceutical product patent protection in some developing countries has actually helped these countries emerge as key players on the global market for pharmaceutical production and trade. In India, which is a global player on the pharmaceutical manufacturing and trade scenes, the Indian Patent Act of 1970 was instrumental in terms of increasing the number of manufacturing firms from 2,237 licensed manufacturers in 1960-70 to an estimated 16,000 in 1992-93. The country's negative trade balance in bulk drugs and drug formulations during the 1970s and 1980s was turned into a surplus by the 1990s (Fink, 2000).

Parallel trade

An important feature of world trade in pharmaceuticals is related to parallel trade, which takes place when significant price differentials occur among trading markets. Traders buy in low-price countries and sell in high price markets. Price differentials usually result from the actions of governments, rather than those of manufacturers or distributors. Pricing policies and patent infringement by 'small countries' could be tolerated as long as markets remain separable, and therefore result in negligible effects on global incentives for drug innovation (Danzon, 1997: 3). Once markets are no longer separable, either because of parallel trade or due to the export growth of patent infringing products, the profitability matrix of the research-based industry is jeopardised.

The globalisation of the pharmaceutical industry

To be better able to respond to the more stringent regulatory conditions in their home markets, particularly in the USA, pharmaceutical companies have been gradually moving towards globalising their operations. Firms first introduce new products in foreign markets in which regulatory conditions are less stringent. This strategy has allowed drug manufacturers to gain knowledge and realise sales revenues on the product, while the new compound is still under regulatory review and development in the home country. Some research-based TNCs have also resorted to undertaking their clinical trials outside of their home countries, but have been faced with institutional barriers. The FDA for example has historically been unwilling to accept data from foreign clinical trials (Grabowski and Vernon, 1976: 49). Pharmaceutical companies also have extensive international production systems. Transnational pharmaceutical firms based in the USA, have an average of 33.8 foreign affiliates per parent firm, which is a larger number than any other of the US manufacturing industries (Maskus, 1998).

The pharmaceuticals industry has adopted a fairly wide range of strategies to have access to overseas markets. The first of these was to cater at arms-length through exporting to these markets. In between the low-risk involved with exporting, and the relatively higher risk of direct investment in overseas subsidiaries, lies a continuum of investment strategies.

The first of these is licensing options, by which a company grants the right to manufacture, distribute and sell a product to another company, together with the technical know-how. The second are marketing agreements whereby a host company takes on the sales management of the product from the 'initiating company'. The difference between marketing agreements and standard license agreements is that the host is not normally given the right to the patented know-how, nor does the arrangement involve any capital agreements such as those associated with joint-ventures. Joint-ventures in turn involve the 'legal' establishment of a jointly owned subsidiary. "This strategy is not widely used in the pharmaceutical industry since marketing agreements generally achieve the same objectives

without the capital expenditure in particularly financing the joint venture" (James, 1977: 27-28).

Establishing off-shore subsidiaries, through direct investment has also been one of the key strategies of pharmaceutical companies. Investing in international production systems fits well with the ownership-location-internalization framework (OLI) of international production. Because research-based pharmaceutical companies are firms with significant knowledge-based assets (patents, trademarks and marketing expertise), taking a direct investment position in the country concerned is in some cases more profitable (Dunning et al., 1978; Dunning 1981). Government policies have also played a powerful role in the decision of pharmaceutical companies to invest abroad. For example, local taxation and financial conditions have played a significant role in corporate decisions to allocate or to increase existing local investment. In France, for example, in order to avoid the problems of harsh currency exchange controls and royalty remittances legislation during the 1960s, firms have opted to establish R&D units in France to utilise profits generated locally. During the late 1960s and early 1970s both Eire and Puerto Rico also provided bases for chemical and finished pharmaceuticals manufactured for Europe and the USA respectively. Both areas have had advantageous investment and training grants tax benefits designed to encourage industrial development and free access to major markets (James, 1977: 27-29).

Research-based pharmaceutical companies, however, tend to be 'nationalistic' in their R&D activities, whereby these activities were usually centralised in their respective domicile markets. Unlike both production and distribution of drugs, "research centers have not migrated to other parts of the world. This part of the industry's core activities remains to be highly concentrated, being located either in the country where the firm is headquartered or in one of the other industry leaders" (Balance et al., 1992: 10). In fact, recent research on TNCs had indicated that TNCs conduct research activities in their foreign affiliates to obtain access to the private knowledge created by local firms. For example, in the Indian pharmaceutical industry, while there has been evidence of technology spillovers from the presence of subsidiaries of research-based pharmaceutical industries, the only firms that have gained from foreign technology spillovers were the

TNCs themselves. Technology spillovers for the operations of TNCs did not affect Indian firms at any level of significance (Feinberg and Majumdar, 2000: 431).

Against the above review, the following section provided evidence that throughout its history, Egypt's generics pharmaceutical industry has remained to operate within the confines of sheer formulation activities. The niche market gained by local Egyptian pharmaceutical companies has always been in the production of multiple-source drugs. This niche market has been expanded and largely facilitated by the absence of pharmaceutical product patent protection in Egypt up to January 2005. None of Egypt's generics pharmaceutical companies has embraced R&D activities, even at modest levels during the relatively inexpensive phase of drug discovery. While Egyptian companies have not advanced in terms of expanding their R&D outlays, their counterparts in India have opted for the more successful path of investing in upgrading their indigenous technological capabilities as well as R&D outlays (Mourshed, 1999), thus eventually differentiating themselves on the global pharmaceutical production and trade scenes.

Egypt's generics pharmaceutical industry has also been losing grounds on the global market by virtue of a diminishing share of total pharmaceutical exports by developing countries. The opposite trend has been observed by India, as well as relatively late comers to the regional pharmaceutical production and trade scenes, such as with the case of neighbouring Jordan.

The remaining part of this chapter provided an in-depth overview of the industrial policy environment within which Egypt's generics pharmaceutical industry has been operating, as well as its growth trajectory during the study period. The coverage also maped the dynamics -if any- of industrial policy governing Egypt's generics pharmaceutical industry on the continuum of industrial policy options as presented in Chapter Two. The performance attributes of this sector in terms of output growth, employment creation, trade performance and R&D activities have also been presented in detail.

3.3 Growth Trajectory of Egypt's Pharmaceutical Industry

Starting from a very modest base comprised of three local companies during the early 1930s, which together covered less than 10 percent of local demand, the Egyptian pharmaceutical industry has undergone significant expansion and growth. Today, the industry meets more than 81 percent of demand in one of the largest markets of the Middle East and North Africa (MENA) region (CAPMAS, 2009). During the long period which elapsed between the industry's formative years and the current phase, one common denominator has persisted across the various policy and regulatory regimes encountered, namely increasing the levels of self-sufficiency. Increasing self-sufficiency was the key criteria used to evaluate the performance of the Egyptian pharmaceutical industry through the socialist regime of the 1960s, the Open Door Policy (ODP) regime of the 1970s and 1980s as well as the ERSAP phase of the 1990s and beyond. The following sections elaborate on the journey of Egypt's pharmaceutical industry, passing through the various policy and institutional regimes, which have governed this industry.

3.3.1 The formative years: the 1930s

The history of local production dates back to 1937, when Bank Misr established the first local pharmaceutical company in Egypt, with a capital of LE 100,000. The new company which was called 'Misr' faced great hardship during its first years of operation, due to competition within what was basically a foreign brand-name dominated home market. It was only during the inter-World War II period that the company began to make positive profits, as a result of the shortage in foreign drug imports. 'Memphis', the second company was established in 1939, with a capital of LE 40,000. Memphis specialized in the extraction of active substances from indigenous local plants (namely Ammidin and Khellin), which were developed by the founder of the company. In 1947, a third local company was established by Egyptian capitalists, and was called 'Chemical Industries Development' (CID) with a paid capital of LE 100,000 (Handoussa, 1974: 60-67).

The three local companies had to compete extensively with their foreign counterparts which controlled 90 percent of the local market in 1952. During the 1950s, 500 foreign pharmaceutical firms and their network of 88 agents, supplied and distributed some 20,000

imported products in Egypt. During this early phase, the government did not intervene in the operation of the pharmaceutical sector, whether in terms of price setting or in terms of import controls. The local market was often flooded by the foreign equivalent of any new local brands of promise. Dispensing chemists were also given large incentives to promote foreign products, by being generously offered free samples as well as supplies for credit (Handoussa, 1974; Academy for Scientific Research and Technology, 1994).

In the aftermath of the 1956 Suez War and the ensuing economic blockade of Egypt, many essential drugs were in short supply, raising awareness of the need for greater levels of self-sufficiency. An important point of departure for Egypt's local pharmaceutical industry followed the creation of the first Ministry of Industry, and the Committee responsible for developing the national pharmaceutical industry in 1957. During the same year, the Higher Organization for Drugs and Medical Requisites was established (Presidential Decree 10/1957) and was headed by the Minister of Health. The Higher Organization was to supervise all matters pertaining to domestic production and supply of pharmaceuticals in Egypt. An independent executive committee was also set up under the auspices of the Ministry of Industry to implement the decisions of the Higher Organization (Handoussa, 1974).

The opportunity to further develop productive pharmaceutical capacity materialized when the Soviet Union offered the Egyptian government substantial loans to be invested in projects of the government's choice. Setting up a huge pharmaceutical complex was proposed, and in January 1958, an agreement to establish El-Nasr Company for the Production of Pharmaceutical Chemicals -as the first state-owned pharmaceutical company- was signed between Egypt and the Soviet Union. During the same year, interest by the government to invite subsidiaries of foreign pharmaceutical companies to set up production facilities in Egypt eventually culminated in three foreign firms being awarded contracts in 1958 and 1959 by the Ministry of Industry to set up foreign majority owned joint ventures locally (Handoussa, 1974).

In March 1959, the Ministry of Industry collected figures on pharmaceutical unit cost of production, and unilaterally decided on a 'cost-plus percentage' for profits.[6] New -lower- prices were immediately enforced, as a result of which some domestic firms found that they were making negligible profits, and the government was obliged to adjust prices upwards. However, domestic firms were still facing hardship in gaining reasonable market shares due to the proportionately smaller profit margin earned by the retailer on domestically manufactured versus foreign drugs. To deal with this problem, the Higher Organization decided to allow for a 19 percent profit margin to the chemist on domestic brands as opposed to 10 percent on foreign brands. Towards the late 1950s, and with government support, the local industry was able to capture 20 percent of the pharmaceutical market. During the same year, the strategic decision to protect local manufacturing prohibited the importation of any product, which was produced by at least three local companies (Handoussa, 1974: 81-82).

In 1960, the Higher Organization was given the sole regulatory authority over the importation of all drugs, pharmaceutical raw material and medical supplies in Egypt (Presidential Decree 212/1960). The Egyptian Organization for Trade in Pharmaceuticals, Chemicals and Medicals Requisites was also established (Decree 1253/1960), and was granted the exclusive privilege of taking control of all pharmaceutical importing agencies, all distribution agencies and all inventories of drugs in Egypt. During the same year, the first five-year plan 1960-65 for the development of the pharmaceutical industry was announced. The key objective of the plan was to increase the level of self-sufficiency from 20 percent in 1960 to reach 65 percent by 1965. The plan stipulated an annual increase of 30 percent in local production, a target which was in fact exceeded during the period specified (Handoussa, 1974; 93).

Evidently, between the early 1930s and end of the 1950s, ensuring the initial survival of the local industry in the midst of aggressive import competition was the key concern of industrialists and policy makers alike. Increasing self-sufficiency levels, and the perception

[6] To date the cost-plus pricing system has been the ruling pricing system in Egypt.

that the pharmaceutical industry was 'strategic', marched hand-in-hand with the emergence of the socialist ideology towards the end of the 1960s.

3.3.2 Nationalization and the move towards ISI: the 1960s

On July 20, 1961 the government took controlling interest in the form of at least 50 percent of capital of the ten largest pharmaceutical companies in Egypt. The ten largest firms to be partially nationalized included CID, MISR and Memphis, which were to maintain their identity and management. Another six firms were merged into two large companies Kahira and Ein Shams (later to be enlarged and renamed Nile), and the tenth was to form the nucleus of Alexandria Company (Handoussa, 1974: 90). Socialism was adopted as the governing economic ideology, import substitution industrialization (ISI) became the dominant industrial paradigm, and the public sector became the arm of the state to achieve rapid industrialization and diversification. Throughout the 1960s, the government set the pace of economic development by being responsible for close to 90 percent of total investment in all modern industries, banks, insurance and construction, while controlling export and import activity (Mabro, 1974: 125).

In July 1962, Presidential Decree 113/1962 established the General Organization for Pharmaceuticals, Chemical and Medical Appliances (GOPCA), taking over the duties of both the Higher Organization for Drugs and the General Organization for Trade and Distribution of Drugs. In 1962, full nationalization of the pharmaceutical industry was completed and COPCA was assigned exclusive responsibility over all matters related to drugs in terms of production, importation, exportation and distribution. Presidential Decree 113/1962 also stipulated that a special committee whose membership includes the Ministries of Health, Industry and Supply was to assume responsibility over pharmaceutical pricing (local and imported). By 1964, four companies, which were producing auxiliary materials used in the manufacturing of pharmaceutical products, were also nationalized and placed under the control of COPCA. Two new state owned commercial companies were established, one for distribution, and another for the supply of chemicals and raw materials (Handoussa, 1974).

Throughout the 1960s, import substitution industrialization was the force driving Egyptian industry, and the pharmaceutical industry was no exception. While export departments were set up in state-owned companies to dispense of surplus output, export activities gained marginal importance. The focus on the local market and the achievement of higher levels of self-sufficiency became the benchmark for successful performance, as a result of which between 1962/63 and 1968/69 local production coverage of domestic demand increased from 53 percent to 86 percent (Handoussa, 1974).

3.3.3 The ODP and the shift towards a private sector led economy: the 1970s and 1980s

An ODP was adopted in 1974, with the investment encouragement Law 43 of 1974 as its legislative foundation. The ODP envisioned "increased economic liberalization and the opening of the Egyptian economy to the larger world market, and the search for outside finance and technology" (Dessouki, 1981: 410). Law 43 was designed to provide adequate incentives to attract foreign capital and technology to a predominately labour surplus economy and to create a synergy of Egyptian skilled labour, Western technology and Arab capital to further develop and reorient industrial production towards outward orientation. Incentives provided under Law 43 were mainly fiscal in nature, with a five-year tax break on corporate profit, extendable to eight years for projects deemed 'special to the economy'. Among the major incentives to incorporate under Law 43 were provisions for exemptions from labour laws, exchange control regulations and from the obligation to obtain import and export licenses (Handoussa, 1993).

The transition from import-substitution industrialization to export-led growth following the ODP in 1974 and beyond was neither smooth nor immediate. Throughout the 1970s and 1980s, the public sector continued to be the dominant player on the Egyptian pharmaceutical production and trade scenes, with inward orientation, the continuation of protectionist measures, price controls and eventually deteriorating financial performance being key features which persisted throughout the two decades (for state-owned companies). Moreover, while the private sector was re-mobilized to participate in industrial activity following the legislation of the ODP in 1974, it was not until the early

1980s that the manufacturing scene saw the entry of private sector pharmaceutical companies, but with marginal export interests. New private sector productive capacity remained predominantly inward oriented, thus adding further competitive pressure on public sector companies.

In general, evaluating the ODP against the objective of mobilizing private (local and foreign) capital produced mixed results. While the new investment legislation after 1974 gradually changed the ownership structure of Egyptian industry in favor of the private sector, it failed to alter its inward orientation. This outcome can be explained against the fact that the shift from an import-substitution/state-led to an export-promotion/private-led industrial drive was not accompanied by a parallel shift in industrial policy instruments needed to provide enough incentives for industries with export potential to actually export. Unlike the East Asian NICs, which have followed a selective approach to industrial development by opting to support particular groups of industries, Egypt's industrial policy since 1974 did not attempt to promote any particular subsector. To the contrary among the criticisms made against the investment encouragement code is precisely the absence of any selectivity in awarding incentives to domestic or foreign investors. The package of generous incentives provided did not discriminate between projects on the basis of field or operation (e.g. consumer versus producer goods or technology intensity or skill intensity) or according to whether the output is intended for the domestic or export market (Handoussa, 1993).

3.3.4 The ERSAP and beyond: the 1990s

In recognition of mounting economic imbalances (Annex 3), and under pressure from the multilateral donor institutions, the government of Egypt initiated the economic reform and structural adjustment program (ERSAP) during the early 1990s. The key pillars of policy change during the early 1990s were trade policy reform, foreign exchange reform, financial liberalization, price liberalization and privatization (Al-Mashat and Grigorian, 1998; Handy, 1998; World Bank, 1998; Abdel-Khalek, 1995; Kheir El-Din and El-Dersh, 1992).

During the onset of ERSAP, industrial policies that can be identified focused on achieving price liberalization, removing quantitative restrictions on imports, trade liberalization, diluting state ownership through privatization and streamlining investment incentives. No conscious effort has targeted the support of new activities that have the potential to expand the capabilities of the Egyptian economy into new areas of comparative advantages (Galal and El-Megharbel, 2005).

Apart from public enterprise reform and privatization, it is safe to argue that in the specific domain of the pharmaceutical industry, the reforms of the early 1990s and associated industrial policy components have only tangentially touched in a positive way on this sector. From an overall perspective, industrial policy within the domain of Egypt's generics pharmaceutical sector continued to serve promoting import-substitution-industrialization by virtue of sustaining non-tariff regulatory trade barriers, as will be elaborated on further. The following sections detail the extent to which the key components of the ERSAP fell short of supporting the generics pharmaceutical industry become more export-oriented, as well as of inducing local companies to upgrade their technological capabilities in preparation for withstanding competition on local as well as on export markets.

Public enterprise reform

Public enterprise reform was based on promoting competition (by liberalizing the prices of factor inputs and output prices), privatizing those enterprises that were not in 'strategic' sectors and a reordering of public investment priorities (Kheir El-Din and El-Dersh, 1992). In 1992, the new 'Public Business Sector' law 230 of 1992 was enacted, relieving all state-owned companies from making contributions to the Treasury other than paying their normal corporate profit taxes as well as indirect taxes. They were also relived from the intervention of relevant line ministries, and were free to make their autonomous decisions regarding output levels, prices, employment, wages, investment and finance independent from central control. The 11 state-owned pharmaceutical companies were treated as Affiliate Companies subject to the new law and were re-organized under the newly created Drug Holding Company. The Drug Holding Company performed the function of the manager of the state's portfolio of assets in its group of affiliated firms, with the main

objective of maximizing the portfolio's present value. The new mandate of what was renamed as the public 'business' sector singled out profit maximization as their main objective function (Handoussa, 1993).

In reality, apart from the reorganisation of the 11 state-owned pharmaceutical companies under the newly established Drug Holding Company, and the re-appointment of top-level management, several of the key constraints of the 1970s and 1980s persisted. This was particularly true with regards the pricing policies governing these companies, and the subsequent evaluation of performance against social rather than economic and financial criteria (Interview, Hussein Zewail, Director, Al-Kahira Company, March, 1999).

During the early phase of the reform program, the relationship between the newly appointed management of what were renamed as public *'business'* sector pharmaceutical companies, the Drug Holding Company and the owner of capital (i.e. the state), became the subject matter of recurrent debate. This was particularly true following the transfer in 1991 of regulatory authority over the pharmaceutical industry, from the dissolved Public Sector Drug Authority to the Ministry of Health. Failure to resolve the issue of ownership versus management in a clear-cut manner played a key role in delaying the reform program as it applied to this sector. The delay was also largely attributed to what has been coined as the 'social mission' of the pharmaceutical industry, be it in public or private hands. This concept in fact defied the logic of the reform process. The review of public business sector company reports released at the eve of the ERSAP, reflected that the newly appointment management of public business sector pharmaceutical companies was made accountable for the difficult tasks of achieving a higher rate of return on investment and maintaining a competitive position on the market compared to the pre-ERSAP period on one hand, while continuing to operate within a distortion ridden policy environment on the other (PEO, 1994).

At the onset of the reform program, questioning whether or not public business sector pharmaceutical companies should concentrate exclusively on attaining higher levels of profitability along lines the private sector was an important policy issue debated during

board meetings of the newly established Drug Holding Company. As the manager of the state portfolio of assets, the Drug Holding Company resolved the debate by fully acknowledging the priority of the social mission governing the operation of pharmaceutical companies under its jurisdiction. The consensus reached was that it remained imperative for public business sector pharmaceutical companies to award greater weight to social versus financial returns, despite the mandate of the on-going ERSAP (Egyptian Drug Organisation, 1992). Evidently, the 'social' responsibility of the industry -as perceived by policy makers- obstructed the full pursuit of profitability objectives along lines the private sector. In application, what this meant was that for public business sector pharmaceutical companies, output price liberalisation fell short of full implementation as will be detailed further.

To date, the decision of meeting social rather than economic targets has had a far-reaching impact on dictating the dynamics and competitiveness levels exhibited by these companies.

Privatisation

Privatisation has been regarded as a core component of the ERSAP, as well as the gateway to increase the autonomy of the newly appointment management of affiliate companies. Initially, criteria set for selecting companies for privatisation included the precondition of having to have positive earnings, minimal restructuring requirements, promising returns on equity, and low levels of outstanding debt. Of no less importance, these companies had to have a minimal numbers of workers to be made redundant. Privatisation in the domain of the pharmaceutical sector was, preceded by the rescheduling of outstanding debts owned by affiliate companies, and an increase in the level of working capital injected through the Drug Holding Company. The implementations of an early retirement scheme,[7] together with placing a hold on new recruitments were also necessary preconditions for successful privatisation (Drug Holding Company, 2005).

[7] Eventually the total number of workers associated with affiliate companies declined from 34 thousand at the eve of the restructuring process to 24 thousand by 2000.

The Drug Holding Company started the privatization of public business sector pharmaceutical companies as late as 1995/96, with Alexandria Company being the first candidate for privatization. In 1995/96, the government sold 40 percent of the shares of Alexandria Company through an initial public offering. In 1996/97 four additional companies have been subject to partial privatization, namely El-Nile, Memphis, ADCO and El-Kahira.

Table 3-1: Privatization status of affiliate companies of the Drug Holding Company

Company	Privatization Status (shares sold)	Value of shares sold
1. Alexandria	40 percent of total stocks	LE 104.5 million
2. El-Nile	33.3 percent of the total stocks	LE 58.2 million
3. Memphis	40 percent of the total stocks	LE 90 million
4. ADCO	40 percent of the total stocks	LE 18.7 million
5. El-Kahira	40 percent of the total stocks	LE 52.5 million

Source: Drug Holding Company, 1995

Plans to also privatise 40 percent of the shares of the Egyptian Pharmaceutical Trading Company, El-Gomhoreya Company and CID by 1998/99 were, however, postponed as a result of the slowdown in the reform program, coupled with the downturn in stock prices during the second half of the 1990s.

While privatisation was a key component of the ERSAP, it is worth noting that as a policy, it was strongly opposed by several members of the Drug Holding Company. Minutes taken during board meetings of the Drug Holding Company which convened during the early years of the ERSAP, document that some members strongly opposed giving up majority ownership in public business sector pharmaceutical companies.[8] The justification given was that the essential as well as the strategic nature of products supplied by these companies, as well as their high social (and hence political) sensitivity, makes it imperative that they remain under full government control. Concern regarding the fact that a large number of workers may be laid off as a result of privatisation constituted an additional hindrance to full privatisation (Drug Holding Company, 1992a).

[8] One of these members has been appointed Aisha Abdel-Hadi as the Minister of Manpower in 2004.

Consequently, the privatisation program as implemented within the domain of pharmaceutical production, proved to be atypical, compared to other sectors of manufacturing activity. While the conservative stance of the Drug Holding Company was indicative of the overall direction the privatisation program was to take within this sector, it was actually the conscious decision of the government to maintain its strong hold over public business sector pharmaceutical companies. The ultimate objective of the government was to control the movement of drug prices in Egypt, at least for the market segment under its direct jurisdiction. The government has in fact, repeatedly exploited its strong hold over the movement of drug prices in Egypt to gain popular appeal. The Minister of Health repeatedly affirmed that the government remains committed to provide affordable medicine to the Egyptian population, regardless of the level of profit (or loss) attained by manufacturing companies, be they in the private or public business sectors (Al-Ahram Daily, 28.11.05). These words echo the same promises which were made by the Minister of Health in 1975 (Al-Ahram Daily, 9.11.75).

The persistence of a large price differential between products of the private and public sectors, has increased the dependency of the government financed social health insurance in Egypt on low priced products supplied by the public business sector pharmaceutical companies (Interview, Hussein Zeweil, Director, El-Kahira Company, March 1999). Pharmaceuticals account for a staggering 60 percent of the cost of government financed social health insurance (compared to the standard world average of 20-22 percent), which currently covers half of the Egyptian population (Al-Ahram Al-Ikesadi, 5.2.96). By retaining full control over supply side actors in the public business sector, especially with regards pricing policies, the government has been able to uphold the social mission which this industry has been historically serving. This mission, would have been clearly jeopardised, had full privatisation of this sector been implemented.

The debate, which took place during the early 1990s, regarding the pace of privatisation in the domain of pharmaceutical production, has remained unresolved. To date, the government repeatedly announces that it will retain majority ownership of public business sector pharmaceutical companies. Privatisation as implemented in the domain of the

generics pharmaceutical industry has had no impact of significance in terms of allowing these companies to achieve higher levels of efficiency as will be presented in detail in Chapter Five.

Price liberalisation

Prior to 1987, 90 percent of the one thousand products manufactured by the state-owned companies in Egypt were subject to price controls. Starting 1992, the process of price liberalization of industrial, agricultural, energy and transport sectors -part of the ERSAP- progressed. Industrial output was divided into groups according to their degree of competitiveness, with market concentration levels, as well as protection being the criteria for measuring competitiveness.[9] Prices of products enjoying subsidized inputs or monopoly output were also set free, except for a small sub-set which became subject to a standard cost formula with an agreed mark-up factor (PEO, 1994). Pharmaceutical products were among those subject to price setting according to a cost-plus formula.

In principle and according to the cost-plus pricing system, all pharmaceutical companies operating in Egypt should be able to guarantee positive earnings. Topping the cost of production submitted to the regulatory authorities with the profit margin specified for essential (15 percent) and non-essential (25 percent) products, has been perceived as a viable and fair system for the pricing of pharmaceutical products in Egypt. The cost-plus pricing system is however marred by pricing rigidities, which result in the aftermath of devaluations and the subsequent increase in the cost of raw material inputs. The fact that the industry imports more than 90 percent of its raw material inputs makes it particularly vulnerable to exchange rate fluctuations.

[9] Products for which the public sector accounted for more than 70 percent of the domestic market (including imports) were regarded as subject of a high degree of market concentration, and hence were viewed as non-competitive. Products enjoying more than a 35 percent nominal tariff protection and/or import bans were considered to be highly protected. Prices of products categorized as 'competitive with low trade protection' were freed in March 1990. Another group comprised of non-competitive products with low trade protection and competitive products with high trade protection, respectively, for which prices were also freed during the same year. Non-competitive products with high trade protection were freed in May 1992.

Public business sector pharmaceutical companies have in fact been trying to adjust to pricing rigidities throughout the 1970s and 1980s.[10] At the eve of the reform program, public business sector pharmaceutical companies were incurring losses on 41 percent of total output (by volume), whereby in 1992/93, the financial burden of loss-making products to affiliate companies stood at LE 87 million (Drug Holding Company, 1994).

Despite the high expectations held by the management of these companies regarding the seriousness of the reform program in addressing the issue of pricing, in 1993/94 loss making products were actually increasing in number with a total of LE 95.4 million in losses. The problem was that the majority of loss-making products were priced when the exchange rate of the Egyptian pound against the US Dollar stood at LE 0.4, compared to LE 2.80 at the eve of the reform program (November 1991). If the prices of these loss-making products were to be adjusted according to actual production cost, a price increase ranging between 200 to 800 percent had to be authorised by the regulatory authorities (Drug Holding Company, 1994). Given the social sensitivity of the industry alluded to earlier, such a price adjustment would have accounted for nothing short of political suicide on behalf of a government taking the first steps towards a reform program.

Throughout the 1990s, practically all of the introductory paragraphs of the annual reports of the Drug Holding Company pleaded with the government to address pricing rigidities, cautioning that affiliate companies may be forced into a situation whereby they will cease to supply the essential drugs needed at the prices imposed (Drug Holding Company, 1994).

[10] The pervasiveness of state subsidies allocated to pharmaceutical products as well as the increase in the number of loss making products were two characteristics of the 1970s and 1980s. Most of newspaper articles published during the first half of the 1970s dealt almost exclusively with issues of pharmaceutical price increases, shortages in supply and government reassurance regarding the continuation of state subsidies, with the state repeatedly announcing that it was committed to ensure that international increases in the prices of pharmaceutical raw material inputs, as well as final products were not passed on to consumers (Al-Ahram Daily, 31.7.74; Al Ahram-Daily, 14,9,74)
By 1985, almost all of the public sector pharmaceutical companies were incurring losses on most products, with an associated implicit subsidy of LE 42 million. The state was also shouldering an additional LE 20 million in costs, as a result of selling imported insulin and baby formula below their import cost (Al-Ahram Daily, 22.2.85:8). Direct subsidies benefiting pharmaceutical products were also pervasive, with 411 products manufactured by public sector companies benefiting from state subsidies in the range of LE 65 million (Al-Ahram Daily, 9.2.1985).

Pricing rigidities violated the principle of price liberalisation mandated by the ERSAP (being in conflict with article 7 of Law 203 of 1991) and represent one form of discrimination between public business sector and private sector pharmaceutical companies (Drug Holding Company, 1998). Discrimination becomes even more stark given the fact that private sector companies established during the 1980s and beyond benefited from tax exemptions on corporate profit for up to ten years, while the public business sector became subject to paying taxes as of 1991 (Drug Holding Company, 2004). Of no less importance, pricing rigidities did not allow these companies to generate acceptable levels of profitability, which in turn did not allow them to invest at acceptable levels in improving technological capabilities.

Trade reform

In 1991, Egypt's tariff structure was streamlined as part of ERSAP. The range of tariffs was narrowed from 0.7-120 percent to 1-100 percent. The number of products subject to export bans was also reduced from 20 to 4, and all export prior approvals on 37 product categories were dropped except for raw cotton and fabrics. Production coverage of import bans was reduced from 37.1 percent of total output, to 22.7 percent in June 1991 (Kheir El-Din and El-Dersh, 1992).

By June 1993, all import bans were removed, except for textiles, garments and poultry, reducing the production coverage of import bans to 4.3 percent of total agricultural and manufacturing output. The tariff rate also went down to 5-80 percent in February and to 5-70 percent in December of the same year. Production coverage by quantitative restrictions declined from 37 percent for agricultural and manufacturing output in 1991 to 4 percent in 1996. In July 1997 the maximum tariff rate was reduced to 50 percent and in January 1998, Egypt eliminated the import ban on textiles, and was committed to eliminating the import ban on clothing by January 1, 2001. Egypt also committed to eliminate all quantitative restrictions on agriculture. In July 1998 further tariff reduction of 10 percent took place (Kheir El-Din and El-Dersh, 1992). In 2007, and in a further wave of tariff reductions, the average weighted tariff rate has been reduced from 14.6 percent to an actual of 6.9 percent in February of 2007 (MOI, 2007).

Unlike the rest of Egypt's manufacturing industries, tariffs on pharmaceuticals have always been relatively low. The reason being that high tariff levels on a vital product such as pharmaceuticals would have in principle been equivalent to taxing the sick. In 1994, the simple average tariff on pharmaceutical products stood at 8 percent, compared to the economy-wide average of 32 percent and the industrial sector average of 27 percent (Subramania and Abd-El-Latif, 1996). By 2005, tariff levels imposed on imports of pharmaceutical products were lowered to an average of 5 percent (Ministry of Finance, 2005). In February 2007, a new tariff schedule was introduced in Egypt, whereby some medicines have been exempted from tariffs.[11] In the new 2007 tariff schedule, tariffs on pharmaceutical products ranged between 2-5 percent depending on the nature of the product.

Despite the low level of tariffs prevailing on pharmaceutical products, non-tariff barriers facing pharmaceutical imports in Egypt remain significant, particularly for products with local equivalents. Non-tariff regulatory trade barriers are manifested in the extent to which registration procedures facing imported products -as administered by the Ministry of Health- are made both stringent and cumbersome. For an imported product to be registered with the regulatory authorities in Egypt, proof of a free sales certificate in one of five of the world top pharmaceutical markets has to be provided by the importer. This requirement has historically ruled out import competition from low cost generic manufacturers in other parts of the world, most notability from India and China.

To illustrate with evidence, and based on data obtained from the Ministry of Health, there are only 21 registered products imported from India and 11 products imported from China on the Egyptian market (Annex 4). In light of the sheer weight of India and China on the world market for generics, the meagre number of products imported from both countries is

[11] These products include antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes. Vaccines for human medicine. Contraceptives; tumours and cancer medicaments; organs transplantation medicaments; cardio vascular medicaments; bilharziasis medicaments; and artificial plasma substitutes; dangerous and chronic, psychological or neurogenic diseases medicaments. Chemical contraceptive preparations based on hormones, on other products of heading 29.37 or on spermicides.

indicative of the extent to which the Egypt's pharmaceutical regulatory regime has consistently hampered the entry of imported generics.

Institutional and regulatory reform

The ERSAP brought further regulatory and institutional reforms to the pharmaceutical sector. From the perspective of the private sector, an important development which accompanied the ERSAP concerned the critical process of pricing. Prior to 1991, the responsibility of pharmaceutical pricing in Egypt fell under the jurisdiction of the Public Sector Drug Authority, thus constituting a clear form of conflict of interest. The reason is that the Public Sector Drug Authority was also responsible for the pricing of all products manufactured by all companies operating in Egypt. This included public sector companies within its portfolio, local private sector companies as well as foreign companies and imported products.

Private sector companies operating in Egypt gained substantially from the restructuring and deregulation which accompanied the ERSAP. In 1992 dissatisfaction with the fact that the Public Sector Drug Authority (which is a competing entity) still retained control over the registration and pricing of pharmaceutical products in Egypt, as well as the approval of the annual production plan was increasingly being voiced by leading private sector companies (SEDCIO, 1992). The transfer of this responsibility to the newly created Central Administration for Pharmaceutical Affairs at the Ministry of Health gave the private sector the opportunity to deal with a more transparent regulatory system compared to the one managed by the Public Sector Drug Authority (SEDICO, 1993). Following the establishment of the Drug Holding Company in 1991, responsibility over all regulatory issues concerning pharmaceutical production -including pricing- was transferred to the Ministry of Health.

The monopoly position enjoyed by the public sector in the domain of pharmaceutical trade and distribution activities was also ended. In 1991, private sector companies (including multinationals) were freed from the obligation to import their raw material inputs through the public sector El-Gomhouria Company, which charged 7-11 percent of the import value

as a fee for the services provided. In addition, the monopoly position exercised by the Egyptian Pharmaceutical Trading Company, the public sector company operating in the domain of pharmaceutical distribution was also ended (Academy of Scientific Research and Technology, 1994).

In light of the above review, it is safe to argue that the pharmaceutical industry has been well responding to the key targets set by the policy regimes under the auspicious of which it has been operating during the study period.

During the 1960s, the targets of import substitution and increasing the levels of self-sufficiency have been fully met in the domain of pharmaceutical industry. In the aftermath of the ODP during the late 1970s and 1980s, investments by private sector pharmaceutical companies, both local as well as foreign have been fully responsive to the opportune investment climate and the relatively large consumer market in Egypt. During the 1990s, the policy regime of the ERSAP phase and beyond did not solicit an outcome from potential as well as current investors in the pharmaceutical sector which was different in any respect from the policy regimes which ruled during the previous decades. Import-substitution-industrialisation remained to be recognised as the key driver for growth. Hence, because individual companies never judged exporting as well as expanding R&D outlays to be beneficial to attaining higher levels of profitability (the key driver in this sector from the perspective of private investors), neither have been actively expanded.

Of equal importance, it has been demonstrated that during the post-ERSAP phase, reforms targeting the pharmaceutical sector in Egypt have mainly been institutional and legislative in nature. The key pillars of ERSAP, namely trade liberalisation, price liberalisation and privatisation actually fell short of full implementation in the domain of the pharmaceutical industry.

3.4 Key Players on the Pharmaceutical Production Scene

A total of 59 pharmaceutical manufacturing companies are currently present on the Egyptian manufacturing scene, including 9 companies which fall under public business

sector ownership, and 8 subsidiaries of research-based companies (Figure 3.1). Since 1979, the Egyptian market saw the establishment of some 42 private locally-owned generic pharmaceutical companies.

Figure 3-1: List of companies present on Egypt's pharmaceutical production scene

	State-owned Drug Holding Company		Subsidiaries of Foreign Research-based Companies		Local Private Sector Companies		
1	**ADCO**	1	**AMGEN**	1	**Acapi**	22	**Marcyrl**
2	**ALEX**	2	**AVENTIS**	2	**Adwia**	23	**Mepaco**
3	**CID**	3	**BMS**	3	**Hikma**	24	**Minapharm**
4	**KAHIRA**	4	**GLAXO**	4	**Amoun**	25	**Multiapex**
5	**MEMPHIS**	5	**NOVARTIS**	5	**Amriya**	26	**MUP**
6	**MISR**	6	**PFIZER**	6	**Arabcaps**	27	**New Life**
7	**NASR**	7	**SERVIER**	7	**Arabcomed**	28	**October Pharm**
8	**NILE**	8	**MERCK**	8	**Army (logistic)**	29	**Opi Pharm**
9	**SEPCO**			9	**Atos**	30	**Pharco**
				10	**Bio-Original**	31	**Pharopharm**
				11	**Borg**	32	**Philopharm**
				12	**Chemipharm**	33	**Rameda**
				13	**Delta Pharm**	34	**Rivapharm**
				14	**EIPICO**	35	**SEDICO**
				15	**Epci**	36	**Sigma**
				16	**European Egyptian**	37	**Simco**
				17	**Eva Pharm**	38	**T3A**
				18	**Global Napi**	39	**Technopharm**
				19	**Haidelyna**	40	**Unipharm**
				20	**Hi Pharm**	41	**Veitopharm**
				21	**Jedco**	42	**Vitapharm**

Source: Ministry of Health, 2008

Subsidiaries of research-based pharmaceutical companies

Despite the fact that this thesis focuses on the generics industry, it was important to diverge and throw light on the presence of subsidiaries of research based companies in Egypt.

When the nucleus of a national pharmaceutical industry was being developed during the 1930s and 1940s, low tariff levels prevailing at that time provided little incentive for multinationals -invited by the Egyptian government as early as 1958- to set up production facilities locally. However, in response to government control of all imports and distribution of pharmaceuticals, this stance was revised, as the alternative of not losing business in Egypt has been to start setting up operation locally (Handoussa, 1974). Pfizer,

Hoechst[12] and the Swiss consortium of Ciba Geigy, Sandos and Wander (Swiss Pharma)[13] established majority owned joint ventures in Egypt. Pfizer and Hoechst began operation in 1962 and Swiss Pharma in 1965. In 1974 BMS entered the Egyptian market, as the first foreign wholly owned subsidiary of a research-based pharmaceutical company, while actual production began in 1979.

During the onset of the ODP, hostility towards FDI in the pharmaceutical sector was acute in Egypt. The principle of allowing foreign companies to venture into the Egyptian market through wholly owned subsidiaries was resisted on the basis that this 'strategic' industry should remain in 'national' hands. This position was actually echoed at the highest levels of policy making. Following the first years of operation by BMS, the sign of hostility towards foreign ownership was reflected in the decision of the Egyptian Syndicate of Pharmacists[14] to freeze direct purchases of foreign products manufactured by the four foreign companies operating in Egypt, and replace them with 'national' products if available. Otherwise, purchases by pharmacies from foreign companies operating locally were to be conducted through the public sector distribution company, and at similar concessions given directly to pharmacies by the foreign companies (Al-Ahram Daily, 7.1.1985).

The initial phase of hostility actually proved to be short-lived. In 1985, local capital was willing to join forces with foreign capital when Glaxo formed a joint venture with ABI (Amoun) marking the -brownfield- entry of the fifth foreign company to the Egyptian market. Between 1990 and 2005, three additional subsidiaries of foreign research-based pharmaceutical companies established manufacturing presence in Egypt.

Together, the eight companies also accounted for 62 percent of the top 100 products sold on the Egyptian market by value, and 42 percent of the top 100 products by volume (IMS, 2005). Six of the eight companies, namely GSK, Novartis, BMS, Aventis, Pfizer and

[12] Currently Hochest Marrion Russel.
[13] Currently Novartis.
[14] The Egyptian Syndicate of Pharmacists is one of the most powerful operators in the domain of pharmaceutical distribution in Egypt.

Servier are among the top 10 companies operating on the Egyptian market, holding 25 percent of the local market by value in 2005 (IMS, 2005).

With almost no exception, these companies realize relatively low levels of financial returns compared to the local private sector (Cairo and Alexandria Stock Exchanges, 2006). Another distinct feature is that despite the fact that foreign companies currently account for 30 percent of Egypt's pharmaceutical exports, the absolute value of exports remained low (Table 3-2). Using Egypt as a low cost manufacturing export base failed to characterize the mandate governing these companies throughout their history in Egypt.

Table 3-2: Pharmaceutical export sales by the three ownership structures operating in Egypt

Sector	99/98	00/99	01/00	01/02	02/03	03/04
Total (USD million)	60.2	52.9	49.2	55.4	50.6	49.4
Public (%)	40.4	10.8	26.6	9.6	5.5	10.3
Private (%)	31.7	65.6	52.8	66.8	66.6	59.7
Foreign (%)	28.1	23.4	20.5	23.6	27.9	29.8

Source: CAPMAS, 2005

Two accusations have often targeted subsidiaries of foreign research-based pharmaceutical companies operating in Egypt. The first pertains to their failure in undertaking any R&D activities locally, while the second is related to the excessive focus on the local market. In fact, evidence suggests that these accusations are not warranted. Foreign companies will only be interested to export out of Egypt if these export activities contribute to their overall financial health. As long as prices and profitability margins in other manufacturing locations exceed those of Egypt, the advantage of having a low cost manufacturing base in Egypt will fail to account for a significant incentive for subsidiaries of foreign research-based companies to use the country as an export spring board (Interview Mohamed Roushdy, Regional Director, Pfizer Middle East, April 2004).

Benefits accruing to Egyptian consumers from the operation of foreign research-based pharmaceutical companies in Egypt are significant. By being present in Egypt, manufacturing has been taking place under license from the parent company, with the support of relatively low cost structure, and hence lower final prices to the consumer. Table

3-3 demonstrates the level of price differentials when comparing products of the research-based pharmaceutical industry imported into the market of neighboring Jordan, with the prices of same products manufactured under license by subsidiaries of research-based companies in Egypt.

Table 3-3: Comparative prices of products manufactured under license in Egypt by subsidiaries of research-based companies and relative import prices in Jordan

	Company name	Trade name	Active ingredient	Conc.	Unit	Filling	Public Price USD
Jordan	Merck	Baneocin oint	Bacitracin	250	IU/g	20g	2.4
Egypt	Biochemie	Baneocin oint	Bacitracin	20 mg			0.9
Jordan	Merck KGaA	Concor 10mg tab	Bisoprolol	10	mg	30	17.6
Egypt	Merck Egypt	Concor 10mg tab	Bisoprolol	10	mg	10	1.7
Jordan	Merck & Co	Singulair	Montelukast	4	mg	28	58.6
Egypt	Merck Egypt	Singulair	Montelukast	5	mg	28	26.6
Jordan	BMS	Capoten Tablets	Captopril	50	mg	30	15.4
Egypt	BMS Egypt	Capoten Tablets	Captopril	50	mg	10	1.6
Jordan	BMS	Megace Oral	Megestrol	40	mg/ml	240ml	166.6
Egypt	BMS Egypt	Megace	Megestrol	40	mg	100	27.6
Jordan	Pfizer	Diflucan caps	Fluconazole	150	mg	1	12.1
Egypt	Pfizer Egypt	Diflucan caps	Fluconazole	150	mg	1	4.2
Jordan	Pfizer	Lipitor	Atorvastatin	10	mg	30	44.7
Egypt	Pfizer Egypt	Lipitor	Atorvastatin	10	mg	7	7.1
Jordan	Pfizer	Zithromax caps	Azithromycin	250	mg	6	21.7
Egypt	Pfizer Egypt	Zithromax caps	Azithromycin	250	mg	6	8.5

Original prices were in local currencies and have been converted to USD
Sources: Jordan Food and Drug Administration, 2006; Egypt IMS Data, 2009

3.5 Market Structure

In 2008, the value of the Egyptian pharmaceutical market stood at LE 13 billion, having multiplied several folds in a span of ten years from LE 1.6 billion in 1991. Imports account for 17.3 percent of the retail market, of which generics account for 50 percent. In 2004, imports accounted for 12.2 percent of the country's LE 6.2 billion market (IMS Egypt, 2009).

Table 3-4: Value of the Egyptian pharmaceutical retail market (LE billion in current prices)

	91	93	95	97	99	02	03	04	05	06	07	08
Retail sales	1.6	2.4	3.1	4.1	4.8	5.8	5.5	6.3	7.9	9.3	10.9	12.6

Sources: Ministry of Health, 2002a; IMS Egypt, 2009

One of the most notable developments of the 1990s was the decline in market shares held by public-business sector pharmaceutical companies, and the gradual increase in the shares of the private sector, both local and foreign.

While the relatively low prices charged by public business sector companies may have worked in favour of increasing turnover and thus market shares, this did not hold true beyond the early 1990s. In the pharmaceuticals sector, marketing is one of the most important of post manufacturing activities, whereby the size of the marketing force employed by competing companies becomes the ultimate 'bottom-line' for successful competition. The absence of direct-to-consumer advertising in the domain of pharmaceutical sales renders "face-to-face" marketing, which entails regular visits to prescribing physicians, one of the most important determinants for gaining market share.

During the 1970s and to a large extent during the early 1980s the mere existence of a product on the market was sufficient for gaining market share. However, during the 1990s, and with the saturation of the local market and the increase in the number of competing products, marketing capabilities emerged as the most important determinant for sustaining, as well as for expanding market shares. Public business sector pharmaceutical companies were simply unable to cope, as a result of which they were always ranked in the 'third-line' after the private sector, whether local or foreign (Interview, Dr. Magedy Hassan, Chairman of Drug Holding Company, January, 2006).

The increase in the number of private sector companies, which were established during the 1980s and the 1990s, was an additional factor, which levied competitive pressure on the public sector. When the private sector began to diversity its line of business from trading to manufacturing activities during the 1980s and 1990s, the "un-written" mandate was to

specialize in the production of drugs which were not already present on the market, or which were being imported. What actually happened was that the newly emerging private sector began to compete with the public sector by manufacturing exact replicas of their already existing product portfolios. Duplication was an easy task in light of the fact that top-level management moved from the public sector to join the newly emerging private sector. The chief executive officer of SEDICO, which is a top ranking local company, was the former general manager of two of the large public sector companies namely CID and El-Nile. The same applies to EIPICO, which is the top ranking local company on the market (2002), whose managing director since establishment was the former manager of Memphis, another public sector company. Both SEDICO and EIPICO commenced production by replicating the product portfolio of the public sector companies they were managing earlier (Interview, Dr. Ali Mohammad, Managing Director CID, May 2004).

In unit terms the market share of public business sector companies declined from 43 percent in 1994, to 23 percent in 2002 and to 18.4 percent in 2008 (Table 3-5). In value terms, their market share declined from 29 percent to 12 percent, and eventually to 10 percent during the same years. The difference between the magnitudes of decline in unit terms, versus value shares, is attributed to the relatively low prices of products manufactured by this group of companies compared to the local private sector as well as to subsidiaries of foreign companies.

Table 3-5: Pharmaceutical Market structure 2004 and 2008 (%)

	Units/2004	Units/2008	LE Sales/2004	LE Sales/2008
Total market (LE '000)	873,498	1,323,496	6,279,026	12,565,859
Public business sector	25.8	18.4	14.9	10.2
Imported	4.4	6.8	12.2	17.3
Multinational	23.5	18.7	28.4	22.4
Private (local generics companies)	46.3	56.2	44.6	50.0

Source: IMS, 2009

3.6 Key Performance Attributes of Egypt's Pharmaceutical Industry

In this section, the key performance attributes of the pharmaceutical industry will be presented. The focus will be on output growth and job creation, export performance and the nature of R&D activities.

3.6.1 Output growth and job creation in Egypt's pharmaceutical industry

The pharmaceutical industry currently accounts for 4 percent of total manufacturing output in Egypt (excluding the public business sector). The relative output growth performance of the pharmaceutical industry does not indicate that this sector has been particularly dynamic in terms of outpacing the rate of growth of total output in the manufacturing sector at large (Table 3-6).

Table 3-6: Manufacturing and pharmaceutical output value in Egypt (LE billion at factor cost)

	98	99	00	01	02	03	04	05	06	07
Manufacturing output	54	62	59	69	71	97	110	130	154	211
Pharmaceutical output	3	3	5	4	3	5	5	6	7	8
Manuf. output growth (%)		15.0	-3.8	17.0	2.8	36.4	13.3	17.7	19.0	36.5
Pharm. output growth (%)		5.2	72.9	-5.2	-21.9	40.8	11.1	0.6	21.2	15.5

Source: CAPMAS, 2009

The pharmaceutical industry in not a labor-intensive industry. Some 22 thousand workers are employed in the pharmaceutical sector (excluding the public business sector), accounting for 2.8 percent of total employment in the -formal organized- manufacturing sector (Table 3-7). Promoting growth in the pharmaceutical industry has, therefore, not been targeting the creation of job opportunities for Egypt's labor surplus economy, but rather to ensure access to pharmaceutical needs though domestic manufacturing and supply.

Table 3-7: Employment in Egypt's manufacturing sector and in pharmaceutical sub-sector ('000)

	98	99	00	01	02	03	04	05	06	07
Manufacturing sector*	590	591	584	594	615	619	638	645	648	801
Pharmaceuticals	11	7	14	13	17	17	19	18	20	22
Pharmaceuticals share employment (%)	1.9	1.3	2.4	2.2	2.8	2.8	3.0	2.9	3.1	2.8
Manufacturing employment growth (%)		0.1	-1.2	1.6	3.6	0.6	3.1	1.2	0.5	23.5
Pharmaceutical employment growth (%)		-31.9	82.1	-9.5	32.6	0.1	13.5	-4.3	9.9	9.7

*In the organized sector Source: CAPMAS, 2009

3.6.2 Trade performance

To date, Egypt maintains a deficit on the pharmaceutical trade balance, with imports standing at LE 887 million and exports at LE 238 million (in fiscal year 2006/07). The pharmaceutical trade deficit has actually been widening, from LE 410 million in 2000/01 to LE 649 million in 2006/07 (Table 3-8).

Table 3-8: Pharmaceutical trade (LE million)

	2000	2001	2002	2003	2004	2005	2006	2007
Pharmaceutical output (factor cost)	4,718	4,472	3,493	4,918	5,467	5,501	6,665	7,697
Pharmaceutical exports	50	49	83	130	209	215	125	238
Pharmaceutical imports	583	499	477	525	627	887	469	n.a
Exports as a share of total output	1.06	1.10	2.38	2.64	3.82	3.91	1.88	3.09

Source: Central Bank of Egypt, 2009; CAPMAS, 2009

In Egypt, export sales remain relatively meagre, particularly when compared to other countries which have begun the development of the pharmaceutical generics industry at much later stages. While Egypt accounted for 1.7 percent of total pharmaceutical exports by developing countries in 1980, this share declined to reach 0.5 percent by 2003. An opposite trend was registered by Jordan, India and China (Table 3-9).

One of the explanations behind the relatively modest pharmaceutical export performance in Egypt finds roots in the public sector legacy. During the 1960s, import substitution industrialization was the force driving Egyptian industry, and the pharmaceutical industry was no exception. While export departments were set up in the state-owned companies to dispense of surplus output, export activities gained marginal importance. The focus on the local market and the achievement of higher levels of self-sufficiency became the "only" benchmark for successful performance. As a result, between 1962/63 and 1968/69 the coverage of domestically manufactured drugs of total demand increased from 53 percent to 86 percent (Handoussa, 1974).

Table 3-9: Pharmaceutical exports as a share of total pharmaceutical exports by developing countries, Egypt and comparator countries

	1980	1985	1990	1995	2000	2001	2002	2003
Egypt	1.68	0.22	0.38	0.57	0.03	0.55	0.67	0.47
Jordan	0.83	1.73	1.97	2.39	1.35	2.11	2.22	1.93
Brazil	1.40	2.90	2.48	2.71	3.21	3.03	2.91	2.86
India	5.16	6.15	14.37	11.73	15.15	14.72	17.92	18.44
China	12.51	11.84	20.40	25.62	21.59	21.60	23.66	26.10

Source: UNCTAD, 2009

Another explanation is related to the fact that a large segment of products manufactured by local generic companies in Egypt are manufactured under license. The output structure of local pharmaceutical companies indicated that a large segment of total output was by default not exportable. In 1980, 20 percent of total output was manufactured under license. By 1995, this share increased to reach 33 percent (CAPMAS, 1997). A standard license agreement clearly states that the sale of products manufactured under license was only authorized within the territory of Egypt. Only a few license agreements allowed for export sales. Unless negotiations allow for wider geographic coverage for products manufactured under license, output is made exclusive to the local market. Almost all of the company executives interviewed confirmed that manufacturing under license is one of the restrictive factors, which does not allow local companies to export. Pharmaceutical registration procedures in importing markets were also among the significant regulatory barriers to exports. In some cases, the cost of obtaining the license to market the product in the importing market reached USD 200,000 with no grantee that the product will eventually get the license (Interview, Mr. Tharwat Abdelshahid, CFO EIPICO, June 1999).

An important reason explaining why local companies have been relatively slow in expanding their export markets is related to the allegation that most of the private as well as the public business sector companies have been incurring losses on a significant number of their products. This has been particularly true following the devaluation of the Egyptian pound in January 2003. No price adjustment has been allowed to accommodate for the increase in the cost of imported raw material inputs. With importing countries stipulating that the price charged for its consumers has to match the price charged on the Egyptian market, if pharmaceutical companies were to export –some products- at the prices charged

in Egypt, this would in fact constitute a direct subsidy to foreign consumers. Pricing remains to be one of the most important export related dilemma's facing pharmaceutical companies in Egypt. The Managing Director of CID, one of the public business sector companies stated that he is incurring losses on most of his products on the Egyptian market, and if he thinks of exporting at the same price as stipulated by importing country regulations, he will in fact be subsidizing the consumers in the importing market at his own expense (Dr. Ali Mohammad, Managing Director, CID, May 2004). This argument has been widely acknowledged by all of the company executives interviewed.

The aggressive nature of competition in export markets is another important deterrent against exporting. The founder of Amoun, which is one of the largest and most successful generic companies in Egypt, admitted that the importance of sales on the local market continues to overweight the importance of export sales. It is an ambitious attempt to expand its international presence during the 1980s and early 1990s, Amoun opened a representative office in New Jersey. The intense level of competitive pressure characterizing the US market, together with the stringent standards imposed by FDA inspections rendered presence on the US market too costly in terms of the required investment. The representative office was eventually closed down, and Amoun's operations on the US market were downsized (Interview, Dr. Tharwat Bassily, Director Amoun, January 2004).

Government support to the industry in its export drive, as represented by the Ministry of Health was also lacking in Egypt. This is particularly true when compared to neighbouring Jordan for example. During his visits to Europe, the late King Hussein, personally supported and followed-up on the registration of Jordanian pharmaceutical products. It was also believed that there is little scope for Egyptian companies to compete in the markets of the EU or the USA, because even if the regulatory hurdles can be overcome, and Egyptian products can compete on the basis of low prices, they cannot beat foreign companies in their marketing capabilities (Interview, Khaled Nosseir, Chairman, Alkan, May 1999).

Other developing countries have achieved high rates of pharmaceutical export growth as a result of allowing the private sector to run the industry much earlier than in the case of

Egypt. Jordan again is a case in point, where the private sector has been able to respond to export opportunities in a much swifter manner than was the public sector of Egypt. It has been argued by public business sector executives during the interviews conducted that if the industry was privately managed since its early days, Egypt would have been among the key players on the global market for generics. There is a marked difference between the speed of response to an export opportunity by a private, versus a public sector company. This was one of the most interesting viewpoints, having been stated by one of the public business sector managers (Interview, Dr. Hussein Zeweil, Director, Al-Kahira, March 1999).

Low levels of export sales by public sector companies can be understood against the fact that economic policy change during the 1970s and 1980s was very slow in altering the import substitution ideology of the 1960s, which was well entrenched as the benchmark for successful performance for public sector companies. Surplus output was mainly stocked as inventory, and was regarded as a strategic hedge against potential shortages. Moreover, export sales were viewed as a waste of scarce foreign exchange resources, particularly since raw material inputs accounted for roughly 40 percent of total manufacturing cost (Interview, Mr. Ahmed Saleh, First Under Secretary, Ministry of Industry, February 1999). Export promotion by public sector companies may have been an objective on paper, but in reality it ceased to be a driving force as an outlet for local production, even at times when inventory levels were already reaching exceptionally high levels of LE 1.1 billion at the eve of the ERSAP (Drug Holding Company, 1992b). A case in point was demonstrated in 1975, when Foad Moheildin, who was then the Minister of Health (later on to become Prime Minster) stated in Parliament that he has issued instructions that export activities by public sector companies should not be at the expense of local needs (Al-Ahram Daily, 9.11.75).

Among the factors which explain the relatively unsatisfactory performance with which Egypt contracted its presence on the world pharmaceutical trade scene was the fact that up to the early 1990s, public sector companies were exclusively responsible for Egypt's export sales, particularly since subsidiaries of foreign companies were not engaged in any export activities of significance. Exporting pharmaceuticals was becoming increasingly difficult for public business sector companies as a result of competition over export markets

becoming intense, especially in terms of having to compete against large companies. Most of Egypt's exports during the 1960s, 1970s and the early part of the 1980s were based on 'barter' trade with Eastern Europe, and therefore there was no element of entrepreneurship with respect to marketing these products outside of Egypt (Interview, Khaled Nossier, Chairman, Alkan, May 1999).

The private sector of the post-1974 period was also not mandated to meet any export targets. When Bristol Myers Squib began to operate in Egypt during the late 1970s, the condition was made that it had to export. However, this condition was not realized. Setting clear export targets was never part of the industrial policy vision governing the industry. The Ministry of Health, in fact penalized Abou Zaabal company, for exporting during the 1970s, as this was judged as a waste of foreign exchange rather than a contribution to foreign exchange earnings (Interview, Mr. Ahmed Saleh, First Undersecretary of the Ministry of Industry, February, 1999). The role of the Ministry of Health was not envisioned to go beyond that of the regulator, being concerned with regulatory issues such as registration, pricing with no serious attempt to promoting the export capabilities of this industry.

Subsidiaries of foreign companies operating in Egypt since the 1960s, never considered exports as part of their operations mandate. For example, Pfizer Egypt does not engage in export activities of any significance. Exports are based on ad-hoc demand which result from the inability of any of the permanent supply-sources to meet the needs in a particular neighbouring market (Interview, Dr. Mohamed Roushdi, Regional Director of Pfizer, March, 1999).

3.6.3 R&D and innovation strategies

None of the generic companies operating in Egypt are involved in pharmaceutical R&D. Local companies conduct 'product development' activities in areas such as formulation development, stability studies for bulk drug and formulations, process development for bulk drugs and the coordination of clinical studies with various Egyptian universities. None of these activities can be categorized as R&D proper. However, from the perspective of a

generics manufacturing firm, it was important to question the extent to which R&D was a crucial element of competitive strategies.

When questioned about expanding the scope of R&D undertaken -as part of the future defence mechanism against the strengthening of the IPRs regime and as publicized by the popular opinion expressed regarding future options available to the industry- local generics companies were actually very candidate in terms of their viewpoint regarding the importance of R&D to their operations. Dr. Tharwat Bassily, the founder of Amoun, which is one of Egypt's largest generic companies, argued that the ability of local firms operating in Egypt to compete on the basis of investing in pharmaceutical R&D was very remote (Interview, Dr. Tharwat Bassily, Founder and CEO of Amoun, January 2004). The same viewpoint was shared by many 'realists' in the industry. According to the former Managing Director of GSK Egypt, it may take two generations or more for Egypt to join the league of innovating countries in the domain of introducing NCE. It was being argued by industrialists that placing pressure on generics manufacturers in Egypt to expand their scope of R&D reflects complete lack of knowledge about the specifics of the single-source drug industry. Innovation is a function of two factors, which are very weak in Egypt. The first is the educational system, which provides the skills needed to support innovation, while the second concerns the necessary financial resources needed to finance the process of product development. In Egypt, these preconditions have been short of the required standards, thus any pressure levied on private sector companies to engage in pharmaceutical R&D along lines the research-based companies indicates unrealistically high expectations (Interview, Dr. Negad Sharawi, Former CEO GlaxoSmithKline, April 2004).

In contrast to the above viewpoints, the Business Development Manager of SEDICO, which is also one of the key players on the generics manufacturing scene, maintained the view that the R&D costs propagated by the research-based industry are exaggerated, which is why he is confident that Egyptian generics companies can well venture into this area. He gave the example of one of SEDICO's top-earning products, which was developed by the company's research team. A copy of this product was also manufactured by another local

generics company, which was eventually acquired by one of the research-based pharmaceutical companies operating in Egypt. The copy of SEDICO's product, became the property of the research-based company, and has been competing in export markets against SEDICO's original product. The interesting part of this story is that the copied competing product, was being sold at three times the price of SEDICO's product on export markets. The justification given was that the research-based company has spent some USD 280 million to develop the product (Interview, Dr. Hossan AboulEnein, Business Development Manager, SEDICO, May 2004).

The inconsistent viewpoints held by manufacturers of generic in Egypt regarding the importance of R&D related investments, falls in sharp contrast with the experience of Indian manufacturers of generics. Ranbaxy, India's pharmaceutical giant which was established in 1961, allocates 6 percent of its sales to R&D. In 2009, Ranbaxy's sales stood at USD one billion. What is important from the perspective of evaluating the performance of Egypt's generics industry is the fact that Ranbaxy followed a track which differentiated it on the world market, having managed to "beat global drug firms at their own game". When Germany's Bayer wanted to develop a once-a-day version of Cipro which is the antibiotic treatment for anthrax, it turned to Ranbaxy. This product now generates USD one million in royalty per month. (Paul Durman, 2004). Ranbaxy is also progressing in the domain of R&D under alliances with giants such as GlaxoSmithKline and Merck (Ranbaxy, 2009).

Low profitability levels associated with pharmaceutical pricing rigidities in Egypt have also allegedly limited the ability of both public business sector as well as private sector companies to allocate sufficient funds to product development, which even for generics manufacturers remains to be of vital importance. To date, public business sector pharmaceutical companies allocate a meager one percent of sales to R&D (Al-Ahram Al-Iktisadi, 2003). Moreover the impact of pricing rigidities on profitability levels played an indirect role in delaying the expansion, rehabilitation and modernization of existing productive capacity as well as supporting R&D even in its most narrow definition. The majority of company executives interviewed complained that losses associated with pricing

rigidities negatively affect their ability to expand productive capacity, as well as to upgrade plant and equipment. Regular inspections conducted by the Ministry of Health (in 1999 and 2000) cautioned that the manufacturing facilities of the Arab Drug Company (ADCO) for example had to be rehabilitated, otherwise, some of the production units may be subject to closure. The reason was that some of ADCO's machinery, which date back to 1963, were still in operation. Foreign licensors have been threatening ADCO to withdraw their licenses, unless concerns regarding the rehabilitation and modernization of the company's manufacturing facilities were to be addressed (ADCO, 2003). Three other companies were judged to be technically incapable of surviving with the current condition of their capital stock, namely, CID, Al-Kahira and Misr (Interview, Dr. Galal Ghorab, Director Drug Holding Company, April, 2004).

3.7 Summary and Conclusion

In retrospect, two key objectives have driven the analysis presented in this chapter. First, in relation to the review of the literature on industrial policy, it was important to throw light on the nature of industrial policy choices governing Egypt's generics pharmaceutical industry during the study period, as well as on their respective outcomes. Second, in relation to the review of the salient characteristics of the world pharmaceutical industry, it was important to be able to identify where such policies have landed Egypt on the world map for pharmaceutical production and trade.

To meet these two objectives, a survey of the literature on the salient characteristics of the pharmaceutical industry was undertaken, and the findings have been contrasted against the survey of the literature concerning the highlights of the growth trajectory of Egypt's generics pharmaceutical industry and its key performance attributes. While secondary sources have been relied upon to undertaken the analysis, a series of unstructured interviews meant to solicit the viewpoints of key players in the policy making and manufacturing circles regarding the research questions posed have been conducted. A review of primary sources of information and data, as present in minutes of board meetings of various companies as well as internal unpublished government documents has also been undertaken.

The exposé presented in Chapter Three yielded the following results. While the majority of Egypt's manufacturing industries have been subjected to the phasing-out of protectionist measures during the study period, in clear contrast, the pharmaceutical industry has benefited from protracted regulatory non-tariff protection. This has been the consistent and most prominent feature of the industrial policy regime governing Egypt's generics pharmaceutical sector. Regulatory protection has allowed local manufacturers of generics to enjoy prolonged exclusive presence on the local market vis-à-vis other low-cost manufacturers of generics from other parts of the world.

While ISI was officially 'shelved' as a policy direction as early as the formative years of the ODP in 1974, to date, ISI remains entrenched as a benchmark against which most companies operating on Egypt's pharmaceutical manufacturing scene evaluate their performance. When policy makers praise the high levels of self-sufficiency achieved by this industry, while neglecting the equally important indicator of success in terms of penetrating export markets, the wrong message is being consistently rallied to the local -as well as foreign- segment of this industry. Incentives for companies to actually export (as demonstrated through the experience of the NICs) have been absent through the study period. The merits of exporting do not just touch on addressing trade balance of issues, but to linking exporting to productivity growth. As detailed in Chapter Two, exporting supports productivity growth through the key channels of economies of scale, efficiency improvements on behalf of exporters through the process of 'learning by exporting', cross-efficiency promotion and resource reallocation from the less to the more efficient firms at the industry level and technical progress, which result from technology spill-overs through foreign contracts and the encouragement of investment in R&D (Fu, 2005; Bartelsman and Domes, 2000). Most, if not all of these benefits have been compromised when manufacturers confined themselves to the local market.

The key changes in Egypt's industrial policy regime during the study period have been primarily concerned with addressing institutional as well as regulatory issues such public sector reform, privatisation, and price liberalisation. Changes on the aforementioned fronts

have only tangentially touched on the performance of the majority of companies operating within the domain of Egypt's generics pharmaceutical industry. Privatisation, as well as price liberalisation -as key components of ERSAP- proved to be circumscribed by the need to sustain the social objective of availing affordable medicine to the Egyptian population at large. The series of institutional and legislative changes brought about by the ERSAP as early as 1991, have also only benefited the public business sector on paper. In reality, this important segment of the industry's manufacturing base remains to be constrained by the most limiting burden of the 1960s and 1970s, namely relegating profitability objectives to secondary importance. This has invariably impacted the overall industrial health of this group of companies, particularly in terms of the resources available to investment in modernising plant and equipment, as well as marketing activities. The outcome has been reflected in the consistent loss in market share as well as relatively modest efficiency levels as will be detailed further in Chapter Five.

A key limitation of Egypt's industrial policy as implemented within the domain of the generics pharmaceutical sector, is that it failed to award any importance to investing in R&D. The outcome was that generics companies failed to see the real merits of R&D investments, having argued that generics firms are not expected to invest in R&D proper along lines the research-based industry. This viewpoint falls in sharp contrast with the rhetoric voiced in Egypt's mass media concerning the need to consolidate financial resources towards unified R&D investments by local companies. The outcome of this policy pitfall is that Indian generics companies have outpaced their Egyptian counterparts in terms of positioning themselves at a far more advantageous position when it comes to competing on what is turning to be a highly aggressive global pharmaceutical market. India generics companies have basically assumed this advantageous position as a result of the government creating a home environment which has forced firms to improve their technological capabilities (Mourshed, 1999).

4. THE BURDEN OF HEALTHCARE EXPENDITURE UNDER THE FRAMEWORK OF EGYPT'S PHARMACEUTICAL REGULATORY REGIME

4.1 Introduction

The regulatory framework governing Egypt's generics pharmaceutical industry is multifaceted. The country's industrial policy regime is one facet of the regulatory framework, while the health care system and its associated framework(s) account for the other.

The main concern of this chapter, is to review the key components of the national drug policy in Egypt. The objective is to throw light on the characteristics of the pharmaceutical regulatory regime, as influencing relative prices on the market. This chapter is, therefore, meant to provide the background against which the research question concerning relative price levels on Egypt's pharmaceutical market will be addressed.

This chapter will also examine the pharmaceutical industry in the context of the Egyptian health care system and how it "interacts" with it, both from a formal perspective (covering the costs and purchasing of medicines by the state/health system) and from the perspective of patients through direct purchases outside the remit of the health system. The objective is to place the findings concerning relative price levels in the context of who shoulders the burden of pharmaceutical expenditure in Egypt.

Among the key findings of this chapter was that while the Egyptian government has been endeavoring to extend the benefits of social health insurance to the maximum number of beneficiaries, Egypt's health care system has remained largely inequitable, leaving close to half of the country's population to be fully vulnerable to potential catastrophic health care expenditure. While 68 percent of expenditure on drugs is shouldered by out-of-pocket expenditure, a clear and coherent generics policy to support alleviating such burden remains to be largely absent. Generics substitution in pharmacies is not formally supported from a policy perspective, nor is it common practice in Egypt. Generics do not attract lower copayments compared to the branded version of the same medicine, whereby under the

umbrella of social health insurance, differential co-payments to promote generic drugs remained to be absent. These findings rendered the research question concerning relative pharmaceutical prices in Egypt both pertinent as well as important.

When writing this chapter, a key challenge faced, was related to the dearth in the body of analytical literature covering the pharmaceutical regulatory regime in Egypt, particularly within the realms of the health care sector. The limited set of available secondary sources on health and national pharmaceutical policies in Egypt -the majority of which are unpublished reports- have provided the basis for evaluating the country's health care system during the study period.

This chapter is divided as follows. Section 4.2 presents an overview of the organization, finance and delivery of health care services in Egypt. Section 4.3 provides an overview health care finance. Section 4.4 outlines the national drug policy in Egypt. Section 4.5 presents the key components of the pharmaceutical regulatory regime. Section 4.6 presents trends in pharmaceutical expenditure and consumption, while Section 4.7 provides a summary of the key findings and concluding remarks.

4.2 Organization, Finance and Delivery of Health Care Services in Egypt

Egypt's population currently stands at 79 million. With some 22 million individuals categorized either as poor or as ultra-poor, and in light of the fact that more than half of the Egyptian population does not have access to social health insurance, ensuring that the health care system delivers equitable and affordable access to medical treatment, and to affordable drugs becomes a necessity for policy intervention. This section looks into how Egypt's health care system operates in terms of organization and finance, with the guiding question being whether or not the current system ensures access to quality health care for all segments of the population, irrespective of their financial means.

The structure of the Egyptian health care system is comprised of a large number of public and private providers and financing agents (Figure 4.1). The Ministry of Health (MOH) is by far the key player on Egypt's health care scene by virtue of being the single major

provider of health care services, as well as *the* regulator of services provision in the country. Other players on the health care scene include the public government sector, the public institutional sector -mainly the Teaching Hospitals Organization (THO), the Curative Care Organization (CCO), the Health Insurance Organization (HIO), and the private sector.

Figure 4-1: Health care providers in Egypt

Source: Nihal Hafez,1996

4.2.1 The government sector

The MOH is the major provider of primary, preventive and curative care in Egypt, through a dense network of 4,300 health facilities (and 66,440 beds nationwide). Public government sector providers receiving direct funding from the Ministry of Finance (MOF) include the MOH, the Ministries of Education, Defense and Interior as well other ministries and public entities directly providing health care services (agriculture, railways and electricity). Some of these government providers are permitted to supplement transfers received from the MOF by charging user fees in special 'economic units', known as 'self-financing units' (Ministry of Health, 2002).

Free subsidized health care services in government facilities are availed to all eligible citizens, through the public delivery systems under the auspices of the MOH, THO and university hospitals. In other words, and in principle all Egyptian citizens have access to 'free' services provided by the MOH facilities. However, medical care outside of a defined

subset of treatments must be paid for out-of-pocket. This subset includes lab fees, and drugs (World Bank, 2009a: 3).

4.2.2 The public institutional sector

The public institutional sector is made up of quasi-governmental organizations in which the state maintains control over the decision-making process. These institutions include HIO, CCOs and THO.

The Health Insurance Organization

The HIO was created in 1964, to provide managed health care services for a constituency of government employees covered by the mandatory government health insurance scheme. When the HIO was created, the objective was to expand its scope of coverage to include the whole Egyptian population in a span of ten years. Judging by the current coverage level, this target proved to be too ambitious.

The HIO delivers health care services through a large network of hospitals, clinics, and pharmacies, as well as by contracting private sector providers. A total of 31.9 million inhabitants are officially under the umbrella of the HIO (HIO, 2010). According to the latest published National Health Accounts (NHA) 2001-02, the HIO accounts for some 5.2 percent of total health care expenditure in Egypt (Partners for Health ReformPlus, 2005: 48).[15] While there are co-payment requirements under the benefits package of the HIO, the package is considered to be very generous, with no limits on the frequency or cost of services. Services provided by the HIO cover all aspects of curative care -including drugs- as well as preventive care for its student and infant beneficiaries. Some 45 percent of expenditure by the HIO is on drugs (Partners for Health Reform, 1997: 17).

The Curative Care Organization

The CCO is an independent organization created following the nationalization of several private hospitals in 1964, and provides health care services to the public for a nominal charge. While maintaining its independence, the CCO falls under the jurisdiction of the

[15] In 2009, a new round to update the NHA was undertaken for 2007/08. The results have not been published.

MOH. The nature of services provided by CCOs are mainly curative in nature, with the revenue-base being fee-for-service, with some free care made available for the ultra-poor patients. The bulk of CCO funding comes from contractual agreements with private and public firms to provide health care services to their employees (Partners for Health ReformPlus, 2005: 40).

The Teaching Hospitals Organization

The THO, is also an independent entity under the direct jurisdiction of the MOH. There are 10 general teaching hospitals in Egypt, which serve a small segment of the population (Partners for Health ReformPlus, 2005: 41). While in principle health care services provided in teaching hospitals are free of charge, including inpatient care, drugs, laboratory and diagnostic services, dental care, in reality patients are more often than not requested to purchase their drug requirements out-of-pocket.

4.2.3 The private sector

The private sector includes for-profit private sector hospitals and clinics, as well as non-profit charity clinics. Pharmacy retail outlets are also considered an integral part of the country's private health care sector. According to the 2001-02 round of NHAs, private health care facilities absorb 54 percent of total health care expenditure in Egypt, while public providers account for the balance (Table 4-1).

Table 4-1: Comparison of expenditures by type of health care provider, 94/95 & 01/02

	1994/95	2001/02
MOH facilities	19%	25.6%
CCO hospitals	4%	0.7%
THO hospitals	2%	1.9%
University hospitals	8%	8.6%
Other ministries hospitals	3%	1.0%
HIO facilities	8%	5.2%
Total, public providers	44%	42.9%
Private hospitals	4%	5.6%
Private clinics	10%	24.9%
Independent Pharmacies	36%	23.2%
Total, private providers	50%	53.7%
Other facilities	5%	3.3%
Total	100%	100%

Source: Partners for Health ReformPlus, 2005

4.2.4 Health care expenditure in Egypt

In 2008, total expenditure on health care services in Egypt accounted for 6.4 percent of GDP, registering a modest increase of two percentage points from 4.7 percent of GDP a decade earlier in 1998. Per capita health care expenditure in Egypt currently stands at USD 333 in Purchasing Power Parity (PPP), a significant increase from USD 150 in 1998. This increase has run parallel to the general improvement in per capita income in Egypt as well as the overall increase in the cost of health care services.

While the Government has been the single key provider and financier of primary, preventive as well as most inpatient curative care in Egypt, since the early 1990s, budget constraints have left government expenditure on health care services as a percent of total government expenditure relatively stagnant (see Table 4-4). Per capita government expenditure on health care remained largely unchanged during the last ten-year period. In 2008, government expenditure on health care services accounted for 38 percent of per capita health care expenditure, compared to 34 percent in 1998.

Out-of-pocket expenditure as a percent of private health care expenditure in Egypt stands at the alarmingly high rate of 95 percent. Table 4-2 indicates that the two largest components of household out-of-pocket health care expenditure by type of provider fall in the domain of private clinics (42 percent) and pharmacies (33 percent). The relatively large proportion of expenditure in pharmacies is explained in light of the facts that a large segment of the Egyptian population resorts to self-prescription, as well as reliance on the pharmacist for medical advice and hence prescription.

The distribution of out-of-pocket expenditures by various cost components indicates that the single largest component of health care expenditure is on drugs, at 43 percent (Table 4-3).

Table 4-2: Distribution of household health care expenditures by type of provider 2001-02

Type of Provider	Percent
MOHP hospitals	3.5
University hospitals	3.1
Other public hospitals	0.9
HIO hospitals	0.8
Private hospitals	9.0
Private clinics	41.9
MOH health centers	3.2
Pharmacies	33.6
Others	4.0
Total LE (billion)	13.6

Source: Partners for Health ReformPlus, 2005

Table 4-3: Annual per capita health care expenditures on various cost components 2001-02

Cost component	Share of per capita expenditure
Hospitals	4%
Doctors	5%
Drugs	43%
Lab	8%
X ray	15%
Transport	2%
Others	24%
Total LE (billion)	13.6

The 'other' category includes a large portion for dental costs
Source: Ministry of Health, 2002a

Table 4-4: Selected ratio indicators for health care expenditure in Egypt

	1995	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
I. Expenditure ratios													
Total expenditure on health (THE) as % of GDP	3.9	5.0	4.7	5.4	5.5	5.9	6.3	6.3	6.0	6.0	6.3	6.3	6.4
Financing Sources measurement													
External resources on health as % of THE	2.7	1.6	1.5	1.2	1.0	0.9	0.8	0.7	1.0	0.9	0.8	1.1	1.1
Financing Agents measurement													
General government expenditure on health (GGHE) as % of THE	46.5	38.2	33.9	39.6	39.6	39.6	39.4	39.1	37.4	37.6	41.0	38.1	38.3
Private expenditure on health (PvtHE) as % of THE	53.5	61.8	66.1	60.4	60.4	60.4	60.6	60.9	62.6	62.4	59.0	61.9	61.7
GGHE as % of General government expenditure	5.3	6.3	6.4	7.2	7.3	7.7	7.6	7.7	7.1	7.1	7.1	7.1	7.1
Social security funds as % of GGHE	25.7	24.8	30.3	24.0	24.3	24.6	25.2	25.0	26.8	26.8	26.9	26.8	26.8
Private insurance as % of PvtHE	1.0	0.6	0.5	0.4	0.4	0.4	0.3	0.2	0.2	0.2	0.2	0.2	0.2
Out of pocket expenditure as % of PvtHE	89.6	93.4	93.5	93.9	94.1	94.5	94.9	95.0	94.9	94.9	94.9	95.1	95.1
II. Selected per capita indicators for expenditures on health													
Total expenditure on health / capita at exchange rate	36	57	59	71	77	75	72	61	62	73	86	101	124
Total expenditure on health / capita at Purchasing Power Parity (NCU per USD)	107	149	150	182	196	217	235	245	246	261	294	310	333
General government expenditure on health / cap x-rate	17	22	20	28	31	30	29	24	23	27	35	39	48
General government expenditure on health / cap Purchasing Power Parity (NCU per USD)	50	57	51	72	78	86	93	96	92	98	121	118	127

Source: WHO, 2010

Table 4-5: Health system expenditure and financing agents' measurement (LE million)

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Total expenditure on health	7,883	9,841	12,891	13,586	16,724	18,853	21,191	23,757	26,335	29,281	32,502	38,930	45,783	55,047
General government expenditure on health	3,666	4,059	4,930	4,610	6,627	7,472	8,393	9,359	10,290	10,962	12,207	15,945	17,424	21,065
Ministry of Health	1,716	2,073	2,583	3,087	3,524	3,961	4,435	5,288	5,400	5,600				
Social security funds	943	1,075	1,225	1,396	1,591	1,814	2,067	2,356	2,573	2,937	3,271	4,282	4,673	5,652
Private expenditure on health	4,217	5,782	7,961	8,976	10,097	11,381	12,798	14,398	16,045	18,319	20,295	22,985	28,359	33,983
Private insurance	43	43	44	44	44	45	45	45	37	42	46	52	62	74
Non-profit institutions serving households	32	29	27	24	22	20	18	17	18	21	23	26	32	39
Out of pocket expenditure	3,780	5,301	7,433	8,395	9,482	10,709	12,095	13,660	15,245	17,390	19,265	21,805	26,959	32,330
Financing Sources measurement														
Rest of the world funds / External resources	215	210	205	200	195	190	186	181	183	279	297	295	519	613
Population (in thousands)	63,858	65,076	66,313	67,573	68,860	70,174	71,518	72,894	74,296	75,718	77,154	78,602	80,061	81,527

"n/a" Used when the information accessed indicates that a cell should have an entry but no estimates could be made.
"0" Used when no evidence of the schemes to which the cell relates exist. Some estimates yielding a ratio below 0.04 percent are also shown as '0'.
Source: WHO, 2010

4.3 Health Care Finance and Insurance

The Egyptian health care system is primarily financed through the government budgetary transfers (38 percent), and individual out-of-pocket payments (62 percent). As a share of the entire government budget, budgetary allocations to the health care sector in Egypt have seen a meager increase from 6.4 percent in 1998 to reach 7.1 percent 2008. Table 4-5 details developments in the contribution of different financing agents to health care finance in Egypt during the 1995-2008 period.

The private household sector (out-of-pocket expenditure) shoulders 62 percent of total health care finance in Egypt (including private employees). Private prepaid plans as a percent of private expenditure on health remain negligible, at less than 0.2 percent. What is worth noting, is that health care finance costs incurred by the household sector have seen a significant increase of 8 percentage points between 1995 and 2008. Part of this large increase has been attributed to the escalation of health care costs in Egypt, and increased demand for private sector services (Partners for Health ReformPlus, 2005: 43). Such an increase is judged to be relatively high in light of two important facts. Firstly, the Egyptian Constitution stipulates that health care in Egypt is theoretically free, or in other words falls under the direct responsibility of the state. Second, and as mentioned earlier, the scale of poverty in Egypt remains significant, with 22 percent of the population being categorized as poor, and 6 percent as ultra-poor (Egypt Human Development Report, 2010). Table 4-6 provides a summary of the system of health care coverage, eligibility and financing in Egypt.

Table 4-6: Health care financing in Egypt: coverage, eligibility and benefits

Population coverage/eligibility	Benefits	Main sources of financing	Main providers
Government health services: all citizens eligible for free subsidized care in the following public delivery systems: a. MOH (central/ governorate level) b. THOs c. University hospital	Comprehensive: primary preventive and curative care, hospital inpatient care, drugs, laboratory and diagnostic services, dental care, chronic care, referrals to tertiary care providers, and limited number of overseas treatment.	a. General revenues, central government budget allocated to MOHP (central and governorate). b. Direct budget transfers from MOF. c. Budget transfers from Ministry of Higher Education and user fees.	Government primary health care units and hospitals of MOHP. For tertiary care, THIOs and university hospitals.
Social Health Insurance (HIO): public and private employees of formal sector, excluding dependents and school children (infants under the new law).	Comprehensive: primary care of GP and specialist services, including home visits, dental, drugs, hospital inpatient care, prosthesis, and physiotherapy.	Employee and employer contributions (payroll tax), tobacco consumption tax for SHIP, household premium (LE4), co-payments, and general revenues (MOF).	HIO facilities, HIO contracted GPs, specialists, clinics and hospitals, including CCOs, MOHP, and private providers (CCOs for vocational school health).
CCO patients a. Employees of companies with CCO contracts b. Accident cases c. Private patients (fee for service) d. Limited number of poor patients (MOH grant)	Services limited to those available within the CCO network, which includes comprehensive curative care.	Government grants for poor patients, service fees and contracts with private enterprises, and HIO.	CCO facilities.
Armed forces, Ministries of Interior and Transport	Not available.	Government budget.	Military hospitals and facilities.
Private sector Households willing to pay for private services.	Variable and is dependent on individual's ability to pay and availability of services in the provider market.	Direct household out-of-pocket payments, limited insurance premiums, and corporate contributions.	Mainly ambulatory care provided by private physicians and clinics and more limited numbers of private/NGO hospitals

Source: WHO EMRO, 2006

4.3.1 The health insurance system

Social health insurance

While the 1952 Constitution stipulates that free medical care is a basic right for all Egyptians, to date, the Egyptian population does not enjoy universal social health care insurance coverage. The publicly-managed health insurance scheme is neither comprehensive nor mandatory for the private sector. Social health care insurance provided by the state, which covers 31 million citizens, remains fragmented by beneficiaries. The current system of social health insurance has developed into multiple programs with different coverage and benefits package for various segments of the population, resulting in what has been described as a patchwork of coverage (World Bank, 2006:17).

With a budget of LE 2.7 billion in 2009, the largest provider of government social health care insurance in Egypt is the HIO (HIO, 2010). Following its creation in 1964, health care coverage to all government employees was made mandatory, while non-mandatory provision of health insurance was also extended to private sector employees.[16] The HIO manages a set of separate compulsory social health insurance programs for its constituency of formal sector workers, pensioners, widows, and schoolchildren, and for infants. The private sector has the option of choosing to benefit from public provision of health insurance under the administrative umbrella of the HIO against an annual fee charged, or to opt for privately managed health insurance. In 1992, Health Insurance Law number 99 expanded the coverage of the public health insurance scheme under the general umbrella of the HIO to all students in their schooling years.[17] Currently, the bulk of the population segment under HIO coverage (close to 80 percent) is comprised of school students and infants. In 1997, all newborns were also made beneficiaries of the social health insurance coverage.

[16] The health insurance scheme for government employees (mandatory) and permanent private sector employees (non-mandatory) is financed by the mandatory monthly subscription of 3% of the payroll for employers and 1% for employees. A nominal fee is also charged upon utilizing the service.

[17] Students' health care coverage is financed through an annual fee of LE 12 per student, covered by the state budget and an annual fee of LE 4 covered by the student. A charge is also taken upon utilizing the service. Health care provision under the public health insurance scheme (HIO) covers all medical services provided by the general practitioner, all services provided by specialists including dental care, hospital care, medical operations and medicine.

Through its network of 13 regional branches, the HIO operates an extensive network of health care facilities for its beneficiaries, and also contracts with public and private providers to extend services for its beneficiaries. The HIO, therefore, functions both as a purchaser and a provider of health care services for its beneficiaries (World Bank, 2006:7).

The copayment component under each category of social health insurance beneficiaries indicates that eligible public and private sector workers, pensioners and widows governed by Insurance Law 79 of 1975 are not subjected to any copayment requirements when it comes to drug costs. For government workers (civil servants) governed by Insurance Law 32 of 1975, a copayment of 50 percent of the cost of drugs is required. For school children and infants governed by insurance Laws 99 of 1992 and 380 of 1997 respectively, there is a copayment of 33 percent on drugs (Table 4-7).

The HIO maintains its own list of drugs for its beneficiaries, providing the guidelines and scope for prescription. This list is periodically revised to include more products as per the needs of patients, and based on the judgment of the Higher Drug Committee of the HIO. Based on the prescription written by physicians in HIO facilities, or by contracted private physicians, drugs are dispensed to patients either in HIO pharmacies, or in contracted private sector pharmacies. In 2007/08, the HIO spent some LE 656 million on drugs, accounting for 45 percent of the total budget (HIO, 2009).[18]

[18] Excluding administrative overhead costs.

Table 4-7: Coverage and eligibility of HIO beneficiaries, 2005

Governing Law	Law 32 of 1975 Workers	Law 79 of 1975 Workers	Law 79 of 1975 Pensioners	Law 99 of 1992 School Children	Decree 380 of 1997 Infants
Beneficiaries	Government workers	Public and private sector workers	Pensioners and widows	Students up to high school	Infants
Number (millions)	3.74	3.29	1.75	16.89	9.14
Payroll tax or annual premium					
Employee share	0.5% of salary	1% of salary	1% pensioners; 2% widows	LE 4 per student	LE 5
Employer/government share	1.5% of salary	3% of salary plus 1% for disability	None	LE 12 for government budget and cigarette tax	
Copayments	GP visit: LE 0.05 Specialist: LE 0.10 Tests: <LE 1 Drugs: 50%	None	None	Drugs 33%	Visit: LE 0.05 Drugs: 33%

Source: World Bank, 2009a

The uninsured segment of the population predominantly belongs to the informal sector and the poor, as well as many dependents of the insured workers and workers in otherwise formal small and medium enterprises (World Bank, 2009a).

Individuals not covered by either public or private health insurance (poor and ultra-poor patients), health care services are mainly provided for free through MOH facilities, university hospitals falling under the umbrella of MOH or private charity clinics (World Bank, 2009a). Because services provided in MOH facilities exclude relatively expensive lab fees and drugs, health shocks and the associated episodes of 'catastrophic' expenditure present an alarmingly high risk of impoverishment for many Egyptian families and individuals.

The state is also considered as the insurer of 'last-resort, whereby the MOH manages a program of treatment at the expense of the state for citizens who are incapable of covering

their medical expenses. Eligibility is considered on a case-by-case basis. In 2008, some 1.7 million patients benefited from free state-funded medical treatment, with a total bill of LE 2.5 billion (CAPMAS, 2010).

Private health care insurance

The market for private health care insurance in Egypt is currently very small. As mentioned earlier, the share of private prepaid plans of private expenditure on health remains low at a meager 0.2 percent of total private expenditure on health. One of the reasons behind such a low share, is that the ruling regulatory environment does not provide an attractive business opportunity for enterprisers operating in the domain of private health insurance. Premiums in Egypt are heavily regulated, and are regarded to be relatively low compared to costs. Another key constraint to the expansion of the health care insurance business in Egypt, is that the governing insurance law guarantees employees the right to refuse to participate in co-payment mechanisms (WHO EMRO, 2006).

4.3.2 The Health Sector Reform Program and establishment of the Family Health Fund

In 1997, the Health Sector Reform Program (HSRP) was launched by the government, marking a new milestone for Egypt's health care system.[19] The key long-term objectives of the Program were the achievement of universal coverage of basic health services for all Egyptian citizens. An immediate priority objective was to target vulnerable population groups for health care coverage. Because of the relatively comprehensive nature of reforms to be undertaken, a staggered approach has been endorsed, with the eventual full implementation of the HSRP to be achieved in a span of 15-20 years (Partners for Health ReformPlus, 2005: 11-12). The Program implementation began with shifting the focus of health care in Egypt from excessive reliance on "vertical programs and inpatient care to a more integrated and less costly primary care model" (Partners for Health RefromPlus, 2005: 3).

[19] The HSRP has been supported by several development agencies, including the World Bank, USAID, and the European Commission.

In 1999, the HSRP initiated a new primary care strategy in 26 accredited facilities, known as Family Health Units (FHUs). The new model included the adoption of the family health care model of service delivery, as well as a package of basic benefits. Cost sharing was a focal feature of the model. Separating health care finance from provision was also began by channeling government finance through a Family Health Fund (FHF), which was established as a nascent public insurance/payer organization, with a mandate to go into contractual arrangements with providers (WHO, 2006).

The FHF has been piloted in five of Egypt's 27 governorates. For utilization control, the FHU facilities charge nominal registration and co-payment fees (with HIO members currently being exempt from such fees). In 2002, and after three years of implementation, some 30 family health units were established, with 75,000 citizens enrolled to receive care in these facilities (Partners for Health ReformPlus, 2005: 4). In 2003, and as part of the HSRP, Ministerial Decree 147 was issued as a step towards outpatient treatment cost-sharing at accredited MOH public health care facilities. Part of the basic health care benefits package, patients pay one-third of the cost of medication (as well as LE 3 per visit). The Decree, nonetheless, included an exemption for the ultra-poor patients who cannot afford (WHO, 2006).

In 2005, a medium-term strategic framework for reforming the health sector in Egypt was unveiled by the government. The strategy has been based on a set of pillars, which included improving the management capacity and financing sustainability of the HIO, as well as expanding social health insurance coverage to all uninsured Egyptian citizens. The fragmented components of the health care system are also to be merged into a national social health insurance system over the medium term (World Bank, 2006: 24).

The above review of Egypt's heath care system yieldrd three clear results. First, and on the positive note, while roughly 50 percent of Egypt's population -irrespective of income levels- have no access to social health insurance, free inpatient and outpatient services provided through the MOH facilities as well as teaching hospitals, provide a viable avenue to ensure access to physicians' consultations as well as inpatient care. Surgeries are also

provided free of charge in these facilities. Second -and on a less positive note-, when it comes to meeting drug needs, patients who are not covered by social health insurance remain increasingly vulnerable to potential catastrophic health care expenditure associated with drug needs, particularly for chronic illnesses. Third, three segments of beneficiaries under the umbrella of social health insurance are obliged to make copayments towards the cost of drugs, namely government workers (civil servants), school children and infants, at 50 percent and 33 percent of the cost of drugs respectively. For chronic illnesses, copayments of this nature remain to be excessively burdensome on these groups of beneficiaries. In Egypt, while the scope of social health insurance coverage remains comparable to countries with similar income levels and government budgetary constraints, the fact that a large segment of the population is fully exposed to the burden of out-of-pocket payment for health care remains to be a serious policy concern. This issue is compounded by the anticipated increases in drug costs as a result of strengthening the countries IPRs regime, as well as impending changes in the pharmaceutical pricing policies as will be elaborated on further in the coming section.

4.4 Overview of the National Drug Policy in Egypt

In 2001, a national drug policy (NDP) was formulated and issued in Egypt, and has been integrated into the overall National Health Policy. To date, the NDP remains at a nascent stage, and still continues to develop over time, with the objective of achieving the dissemination of NDP strategies and concepts to the constituency of stakeholders in the health sector. The key components of the pharmaceutical policy in Egypt -particularly in terms of organization and regulation- can be summarized in the following points: list of essential drugs, pricing that targets the balance between equity and profitability; number of products on the market; drug registration; and the local pharmaceutical industry (MOH, 2003).

Egypt's national drug policy remains to be an aspiration for a roadmap, rather than a clear and coherent 'commitment to a goal and a guide for action', expressing and prioritizing goals set by a government for the pharmaceutical sector, as well as identifying the main strategies for attaining these goals. According to the World Health Organization, a national

drug policy document is presented as an official government document, which covers the aspirations, objectives and commitments of various stakeholders. The core value of a national drug policy document is that it outlines the national goals and objectives for the pharmaceutical sector, as well as the strategies to meet these objectives. Key common denominators in all national drug policy documents include the objectives of ensuring equitable access, good quality and rational use of drugs. The various components of a national drug policy document are linked to these key objectives (WHO, 2001: 6-7). Table 4-8 provides a list of the key components of standard national drug policy documents, indicating their relevance to the three main objectives of the policy.

Table 4-8: Components of a national drug-policy linked to key policy objectives

Components	**Objectives**		
	Access	**Quality**	**Rational use**
Selection of essential drugs	X	(X)	X
Affordability	X		
Drug financing	X		
Supply systems	X		(X)
Regulation and quality assurance		X	X
Rational use			X
Research	X	X	X
Human resources	X	X	X
Monitoring and evaluation	X	X	X

X= direct link; (X) indirect link
Source: WHO, 2001

As the key element of Egypt's national drug policy have been covered in the previous sections, the following sections will present an evaluation of the extent to which the various elements of Egypt's national pharmaceutical policy -which can be captured- fulfill the objectives of access, quality and rational use as outlined in the table above, for all consumers of pharmaceuticals in Egypt.

4.4.1 Essential drug list

The concept of essential drugs is "that a limited number of carefully selected drugs based on agreed clinical guidelines lead to more rational prescribing, to a better supply of drugs and to lower costs" (WHO, 2001). The first Essential Drug List was issued in Egypt in

1998, with the objective of ensuring that essential pharmaceutical products included in the list are available "when" and "where" they are needed. The list has also helped reduce the number of drugs and lower their cost for beneficiaries of social health insurance. Tendering drug requirements for mandatory social health insurance, helped obtain these products at significant discounts. The Essential Drug List has been updated in 2006, in order to comply with the strategy of the MOH. As mentioned earlier, beneficiaries of the social health insurance scheme, however, have access to medicines listed on the HIO drug list, which is not identical to the Essential Drug List. Similarly, the drug list for HSRP pilot sites which is being used for the outpatient facilities -under the umbrella of the Basic Benefits Package- is different from the MOH Essential Drug List (WHO, 2006).

In Egypt, the majority of the population are treated with drugs prescribed by physicians who fall outside of the remits of the social health insurance system, and are paid for out of pocket. One of the key problems with the essential drug list, is that there has not been any effort to promote the essential drug list concept in the private sector in Egypt. The concept of an essential drug list in the private sector health care sphere in Egypt is totally absent. This fact, together with the relatively larger marketing budgets of manufacturers of expensive drugs, has ultimately meant that patients are more often than not prescribed relatively high priced drugs, in small quantities, rather than therapeutic amounts of essential drugs (WHO, 2001).

4.4.2 Strategies to increase pharmaceutical affordability in Egypt

One of the key challenges of any health care system is to ensure that pharmaceutical prices are affordable, whether in the public or private sectors. The challenge of ensuring affordable pharmaceutical prices is amplified due to the fact that market failure is prevalent. On one hand, information imbalances are caused by the patient knowing less than the prescribing physician or the dispensing pharmacist about the efficiency and appropriateness of the drug to be consumed. On the other hand, competition failure related to production being concentrated in the hands of a few suppliers is the ultimate outcome of market power being entrenched through exclusive rights related to patent protection (WHO, 2001). To

'dilute' the market failure related implications in the domain of pharmaceuticals, and in order to ensure affordability, prices are usually regulated by governments.

In Egypt, the regulation of drug prices has been at the core of the controversy over industrial policy toward pharmaceuticals (Nathan Associates Inc., 1995:3). The majority of industrialists as well as policy makers interviewed during the course of writing this thesis have argued that pharmaceutical pricing policy in Egypt remains to be a key component of the government strategy to ensure drug affordability, thus serving a health rather than an industrial policy objective. The following section explores the key components of strategies to increase drug affordability in Egypt, including pricing policy.

Pricing

Pharmaceutical products in Egypt are priced on the basis of a cost-plus formula, in order to ensure both the affordability of medicine and to guarantee a positive profit on all drug products sold on the Egyptian market (Nathan Associates, 1995:4). Cost-plus pricing has been the standard pricing model in Egypt since the inception of local pharmaceutical manufacturing activities during the 1930s (Handoussa, 1974). The Pricing Committee of the Central Administration of Pharmaceutical Affairs (CAPA) of the MOH is responsible for price setting on the basis of reviewing the cost sheet presented by applicant firms to determine ex-factory prices for locally manufactured products, and importer-to-distributer prices for imported products.

For a locally manufactured product to be priced, a pharmaceutical company submits a cost sheet including direct manufacturing costs, which are categorised into the cost of raw material inputs, packaging material, and overhead costs. Direct costs are then topped with a series of other indirect cost items (Table 4-9), as well as with the profit margin of the manufacturer to eventually reach the x-factory price. For imported products, the free-on-board (FOB) prices which are submitted to the Pricing Committee of the CAPA, including the price in the country of origin presents the basis for the pricing add-ons to eventually reach the importer-to-distributer price (Table 4-10). The Pricing Committee is mandated to compare the suggested price submitted by companies with the prices of similar products of

competing companies, as well as against a list of international prices for raw material inputs (Interview, Dr. Gamila Moussa, Director, Central Pharmaceutical Affairs, March 1999).

Pharmaceutical pricing does not differentiate between local products manufactured by subsidiaries of research-based companies with manufacturing presence in Egypt and local generics companies. If a product is manufactured under license in either case, then a royalty fee of 11.6 percent is included in the indirect cost items. The difference in the final price is, nonetheless, heavily impacted by the fact that subsidiaries of research-based companies operating in Egypt import their raw material inputs from the mother company, which means that this direct cost component is usually higher than for generics companies, as they are able to source their raw material inputs from less costly sources.

The profit margin ceiling is 15 percent for essential drugs, 25 percent for non-essentials and 40 percent or more for over the counter drugs. The cost sheet is then topped by a distribution mark-up (7.86 percent), pharmacists' mark-up (25 percent) a sales tax (5 percent of ex-factor price). The public (retail) price for local products is 45.5 percentage points above the ex-factory price. Once a price is set, it is rarely re-evaluated to account for any adjustments in cost, and has to be approved by the Prime Minister. Prices submitted by companies in response to tenders either by the government or private hospitals, usually provide significant discounts which can go up to 50 percent of the retail price for a product.

Table 4-9: Pricing list of local pharmaceutical products according to Ministerial Decree 314 of 1991

Raw material(s) cost
Packaging materials cost
Direct salaries (up-limit)
Total direct costs
Indirect industrial expenses 20%
Financial & administrational expenses 30%
Marketing expenses 15%
Research expenses 3%
Scientific office expenses 11.6% (in case of products under license)
Royalty expenses 11.6% (in case of products under license)
Total costs
Manufacturer's profit (15% or 25 %)*
X- Factory Price
Payment in cash 4.5%
Distribution expenses 7.86%
Wholesaler Price
Pharmacy profit 25%
Sales taxes **
Medical stamps
Retail price

** 15 % Profit for essential drugs and 25 % profit for others ** 5 % from x- factory price*
Products indicated for treatment of chronic or life threatening diseases are exempted from sales taxes
Source: Drug Planning and Policy Center, 2009

Table 4-10: Pricing list for imported pharmaceutical products according to "Pricing Criteria" approved by the Minister of Health (in 30/8/1988)

Trade name: Dosage form:
Importing company: Pack:
Foreign manufacturer: FOB (or CIF) price in foreign currency:
Exchange rate: FOB (or CIF) price in L.E.

F.O.B Price in LE
Cost of freight 5 % OF F.O.B price
Insurance 1% OF FOB price
C.I.F. Price
Bank Charges 1% OF FOB
Customs duties *
Clearance charges & internal transportation 0.55% of CIF
Total Cost / Unit
Importer profit 6.4%
Price of the importer to distributer
Distributor Profit 7.53%
Wholesaler price
Pharmacist Profit 13.64%
Public price before adding taxes
Sales Taxes**
Medical Stamps (2% of public price without taxes)
Retail Price

** 5 % of CIF price ** 2 % from public price without taxes Products indicated for treatment of chronic or life threatening diseases are exempted from customs duties and from Sales taxes*
Source: Drug Planning and Policy Center, 2009

In 1991, and as part of the reform program, Ministerial Decree 314 of 1991 was issued, according to which pharmaceutical prices were to be reviewed bi-annually (or when needed) to accommodate for inflation and devaluation. While the cost-plus pricing formula has been meant to guarantee a positive profit on all drug products, in reality all manufacturing as well as importing companies have been complaining about the rigidity of pricing policies in the face of increasing production costs associated with inflationary pressures as well as currency fluctuations. In response to inflexibilities exercised by the regulatory authorities to revise prices to adjust to inflation and devaluation, drug manufactures in Egypt have managed to deal with stringent price re-evaluations by resorting to a process called 'vintaging'. Vintaging means "that identical products introduced at different times will be sold at different prices, with the more recent 'vintage' of products being sold at a higher price" (Nathan Associates, 1995:6).

Current market data indicates that the more than one-third of pharmaceutical products on the Egyptian market are priced at less than LE 5 (Table 4-11).

Table 4-11: Price categories for all registered pharmaceutical products up to April 2008

Price category	Percent of registered products
Less than LE 5	34.59
From 5-10	24.38
From LE 10-20	16.56
From LE 20-30	6.56
From LE 50-100	4.96
From LE 100-500	4.56
From LE 30-40	4.28
From LE 40-50	2.81
From LE 500-1000	0.78
From LE 1000	0.78

Source: Bayoumi, 2008

In an unprecedented move by the Minister of Health, Ministerial Decree 373 was issued in 2009 to change pharmaceutical pricing in Egypt, ushering a storm of controversy regarding its impact on drug prices. Ministerial Decree 373 of 2009 stipulated a change in the cost-

plus pricing system in Egypt. Prices for innovative products will be set at 10 percent less than the lowest-priced version available in 36 reference markets. The decree mandates the Ministry of Health to consult prices in reference markets in order to issue local prices. As for generics, prices are to be set at a fixed percentage markdown of innovative drugs. Ministerial Decree 373 provided three categories of generic drugs, as per the good manufacturing practices (GMP) certifications to be obtained by applicant companies. The first category of generics, which are to be priced at 30 percent less than their brand-name equivalents, includes products of companies with manufacturing facilities licensed by the Ministry of Health and certified by international agencies. The second category of generics will be priced at 40 percent lower than their brand-name equivalents. This category includes generics manufactured by companies with manufacturing facilities only licensed by the Ministry of Health. The deadline for these companies to also receive quality accreditation from international agencies is set for the year 2020, after which failure to receive accreditation will result in the closure of their manufacturing facilities. The third category of generics to be priced at 60 percent lower than their brand-name equivalents includes drugs manufactured under toll-manufacturing agreements. Toll-manufacturing is prolific in Egypt, whereby companies that do not have their own manufacturing facilities, lease production lines from other companies that are not fully utilising their manufacturing capacity.

A legal case to stop the attempt to change pharmaceutical pricing in Egypt has been raised by the Egyptian Initiative for Personal Rights. In April 2010, Egypt's Court of Administrative Justice issued a ruling to suspend work under the new drug-pricing system. The legal case has been based on the contention that for locally manufactured generics, the new pricing system has been judged to unnecessarily tie drug prices in Egypt with global prices that do not reflect manufacturing costs in Egypt, nor accommodate for the country's low income levels (Egyptian Initiative for Personal Rights, 2009).

Additionally, among the key flaws of the new pricing decree, is that it does not refer in any way to the pricing policy when it comes to products manufactured under license by subsidiaries of research-based companies present in Egypt. By moving away from the cost-

plus system, which reflects Egypt's low cost of production manufacturing base, products manufactured under license by subsidiaries of research-based companies will be priced according to the lowest-priced version in reference countries. If research-based companies further centralise their manufacturing facilities -as is currently the case- in Europe and North America, tying up prices in Egypt to prices in these relatively high cost of production locations, will ultimately mean that average price levels of products manufactured under license by subsidiaries of research-based companies currently present in Egypt will increase.

Tariffs and taxation

As mentioned earlier (Chapter Three) tariff levels imposed on imports of pharmaceutical products in Egypt have always been relatively low. Tariff levels currently range between 2-5 percent depending on the nature of the product (Ministry of Finance, 2005).

The sales tax on pharmaceutical products stands at 5 percent of the x-factory price for local products and at 2 percent from public price for imported products. Local and imported products indicated for the treatment of chronic or life threatening diseases are exempted from sales taxes.

Promoting competition in the multiple-source drug market, including generic substitution

Using generic names is an important strategy to promote price competition between products manufactured by different companies in the multi-source drug market. A clear policy of using generic names in the public and private sectors is meant to reduce drug costs as well as increasing drug availability and consumer access (WHO, 2001: 34). Promoting the use of generic drugs can be achieved through various avenues, including the competitive bulk procurement using generic name for essential drug programmes, as well as the promotion of price competition in the private market through generic prescribing and generic substitution. Four key factors do influence the use of generic drugs in any particular market, namely supportive legislation, quality assurance capacity, acceptance by prescribers and the public, and economic incentives (WHO, 2001: 35).

Promoting competition among equal medicines from different sources through the usage of generic names in Egypt is practically absent in the private health care sector. Physicians practicing in the domain of the private health care sector in Egypt do not prescribe on the basis of generic names.

In addition, from a legislative and regulatory stance, until the end of the study period in 2008, no more than four identical products in terms of therapeutic value and dosage forms were allowed registration and marketing authorisation on the local market. The exception, however, was for production for export sales or for public tenders on the local market. If a company wishes to introduce a new product in excess of the specified limit of four, the suggested retail price has to be 25 percent less than that for similar competing products (Interview, Dr. Samia Saleh, Director, CAPA, May 2007). While the logic of such restriction is primarily geared towards limiting the degree of confusion a prescribing physician may face when having to choose between a relatively large numbers of generic products, such a limitation has invariably worked against promoting price competition between various suppliers on the Egyptian market.

Because the use generic names is virtually absent in the domain of the private health care sector in Egypt, dispensing pharmacist do not engage in the practice of generic substitution. In addition to placing a limit on the number of products sharing the same therapeutic value, generic substitution is practicality absent in Egypt. Due to the relatively small size of private health care insurance schemes in Egypt, economic incentives whereby reimbursement in insurance schemes is based on the promotion of low-cost generic equivalents also remains absent.

4.5 Pharmaceutical Regulatory Framework

The main tasks of a drug regulatory authority are to ensure the quality, safety and efficacy of drugs and the appropriateness of product information. The core elements of drug regulation include quality, safety, efficacy and information (WHO, 2001).

The regulation of the pharmaceutical sector in Egypt currently falls under the jurisdiction of the MOH. Several laws, decrees and regulatory measures govern the registration, marketing authorisation, production, pricing, and sale of pharmaceutical products in Egypt.

The Egyptian Drug Authority (EDA) is the pharmaceutical regulatory entity within the MOH performing the key services of license provision, registration, medical custom releases and pharmaceutical inspection. The EDA is the institutional umbrella for three bodies, namely the Central Administration for Pharmaceutical Affairs (CAPA), the National Organization for Drug Control and Research (NODCAR) and the National Organisation for Research and Control of Biologicals (NORCB). The three organizations, CAPA, NODCAR and NORCB cooperate in managing the registration, pricing and marketing authorisation of pharmaceutical products in Egypt. Administrative functions are undertaken by the CAPA, laboratory and bioavailability analysis are undertaken by NODCAR, while the safety and efficacy of all imported and domestic biologicals falls under the responsibility of NORCB (EDA, 2010).

Licensing of pharmaceutical manufacturing establishments

For a pharmaceutical company to commence operation in Egypt, a license has to be granted by the EDA, through the General Department of Pharmaceutical Licenses. The manufacturing site is visited by relevant committee members from EDA, to verify that that the factory is compliant with the requirements of WHO GMP (EDA, 2010).

Registration

For a pharmaceutical product to be registered, an application for registration is to be submitted to the Registration Committee of the CAPA for approval. The application reviewed by the Technical Committee of CAPA along with product documentation, and finally a sample is analysed in the labs of the NODCAR for a variety of tests which include physical, microbiological, and pharmacological and bioavailability, involving human volunteers. The requirements for the completion of the registration file for pharmaceutical products in Egypt differ, depending on whether the product is imported or manufactured locally. The set of common required documents include the full scientific file of the

product, including the formula, pharmacological, toxicological and clinical studies as well as stability data (EDA, 2010).

While imported pharmaceutical products are segmented into originator products and generics, the registration form is the same for both. Similarly, while local products are also categorised as either 'new' (originator) or generic, the registration form for both products is the same. New local products are those manufactured under license by subsidiaries of research-based companies with manufacturing presence in Egypt.

For imported products to be registered, providing a free sales certificate for the product from the FDA in the USA, EMEA in Europe, JPMA in Japan or evidence that the company is a member of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, is the basis on which a product may be approved for registration in Egypt (EDA, 2010).

For local products to be registered, in addition to the standard documentations required, in case the product is being manufactured under licence -as with the case of any new product to appear on the market- the license agreement has to be submitted, as well as the free sales-certificate of the product in the country of origin. For registration to be completed, the average time-frame is four months.

Marketing authorisation and number of products on the market

The CAPA of the EDA is exclusively responsible for granting marketing authorisation for pharmaceutical products. Following the completion of the registration files, the length of time and nature of processes for granting marketing authorisation in Egypt depends on the nature of product being considered. On average, it takes from 5-6 months for imported products to obtain marketing authorisation. For new local products, as well as for generics the time-span for obtaining marketing authorisation is 8 months.

Procedures for granting marketing approval for an originator product include the provision of documentation from the Egyptian Patent Office concerning the patentability status of the

product. For generics, a similar document has to be obtained from the Patent Office indicating that the product is not under patent protection.

Regarding new conditions put forward by the CAPA for granting marketing authorisation for generic products, the most important change which occurred following the enactment of the TRIPS-consistent Patent Law 82/2002, was the requirement that for any product to be granted marketing authorisation, a certificate from the Egyptian Patent Office has to be provided, clearly indicating that the product is not currently under patent protection. Providing a free sales certificate in one of the reference markets is the basis on which a generic product may be approved for registration in Egypt.

From the angle of promoting competition, Egypt's TRIPS consistent Patent Law 82 of 2002 allowed generic manufactures to use patented inventions for the purpose of "*preparing*" to obtain marketing approval prior to patent expiration. Patent Law 82 allows generic companies to proceed during the period of patent protection of a product, with the manufacturing, assembly, use or sale, with a view to obtain a marketing license, provided that the marketing starts after the expiry of such a protection period.

A total of 7419 registered products are currently present on the Egyptian market, of which 82 percent are manufactured locally, and 18 percent are imported (Bayoumi, 2008). Before 2009, no more than four identical products in terms of therapeutic value and dosage forms were allowed sale on the local market. The exception, however, is for production for export sales or for public tenders on the local market. If a company wishes to introduce a new product in excess of the specified limit of four, the suggested retail price has to be 25 percent less than that for similar competing products (Interview, Dr Samia Saleh, CAPA, May 2007).

4.6 Trends in Pharmaceutical Expenditure and Consumption

In Egypt, total pharmaceutical expenditure (in the private retail sector) increased from LE 1.6 billion in 1991, to LE 6.3 billion in 2004 and to LE 12.6 billion in 2008. This

significant increase is attributed to increased demand for health care services in Egypt, rather than to inflationary pressures.

Public and private pharmaceutical expenditure

According to Egypt's NHAs, pharmaceutical expenditure (expenditure incurred at health care facilities as well as independent retail pharmacies) accounts for 37 percent of total healthcare expenditure (Table 4-12). Private out-of-pocket expenditure on pharmaceutical products accounts for 68 percent of total expenditure on pharmaceuticals (Partners for Health ReformPlus, 2005: 54).

Table 4-12: Summary of pharmaceutical expenditure, 2001-02

Summary	LE	Percent
Total pharmaceutical expenditures	8,584,524,962	37%
Total health care expenditure	23,081,139,867	
Public pharmaceutical expenditure	2,715,134,099	32%
Private (households) pharmaceutical expenditure	5,869,390,864	68%
Total pharmaceutical expenditures per capita	129	
Total expenditure on drugs at retail pharmacies	5,360,745,709	62%
Total expenditure on drugs administered at care at health facilities	3,223,779,252	38%

Source: Partners for Health ReformPlus, 2005

The MOH is the largest public entity expending on pharmaceutical products in Egypt, followed by the HIO and university hospitals (Table 4-13).

Table 4-13: Distribution of drug consumption 2001-02 (LE)

	Total pharmaceutical consumption
MOH	1,361,030,856
HIO	701,653,559
CCO	29,618,500
Universities (MOHE)	511,612,787
HIO	41,653,100
Public firms	65,643,111
Total public	**2,711,211,979**
Total private	**5,869,487,251**
Grand total	8,584,524,962

Source: Partners for Health ReformPlus, 2005

4.7 Summary and Conclusion

The key concern of this chapter has been to review the components of the national drug policy in Egypt, with the objective of throwing light on the characteristics of the

pharmaceutical regulatory regime, as it influences relative prices on the market. This chapter provided the background and context against which the research question concerning relative price levels on Egypt's pharmaceutical market will be addressed.

This chapter also examined the pharmaceutical industry in the context of the Egyptian health care system and how it "interacts" with it, both from a formal perspective (covering the costs and purchasing of medicines by the state/health system) and from the perspective of patients through direct purchases outside the remit of the health system. The objective was to place the findings concerning relative price levels in the context of who shoulders the burden of pharmaceutical expenditure in Egypt.

Based on a limited set of available secondary sources on health and national pharmaceutical policies in Egypt, among the key findings of this chapter has been that while the Egyptian government has been endeavoring to extend the benefits of social health insurance to the maximum number of beneficiaries, Egypt's health care system remains largely inequitable, leaving close to half of the country's population to be fully vulnerable to potential catastrophic health care expenditure.

Of equal importance from a policy stance, and despite the fact that Egypt has the largest generic manufacturing base in the Middle East and North Africa region, as well as the largest consumer market, the review of the country's health care system and pharmaceutical regulatory regime indicates that a clear and coherent generic policy remains to be largely absent. While 68 percent of expenditure on drugs is shouldered by out-of-pocket expenditure, a generics policy to support alleviating such burden remains to be largely absent. The exclusion of pharmaceutical products from patentability, was perhaps the most easy to capture component of supply-side related generic policy in Egypt. Such exclusion from patentability has primarily targeted supporting access to affordable drugs rather than supporting the pharmaceutical manufacturing base from an industrial policy perspective. While a 20-year period of pharmaceutical patent protection has been enforced in Egypt since January 2005, Bolar-kind of practices are, nonetheless, allowed under Patent Law 82 of 2002, in a clear stance of supporting generics penetrate the market once a patent

expires.[20] Marketing authorization in Egypt, however, remains to be largely indifferent as to whether or not a product is an originator brand or a generic product, particularly from a timeframe perspective. In other words, generics do not follow an accelerated track for obtaining marketing authorisation.

Supporting the penetration of generics by verture of a lax patent regime has been the most "easy to capture" component of generics policy in Egypt. However, if such support is not matched with clear policies which target iliciting increased demand for gnerics on behalf of prescribing physisians, insurares and consumers, then the outcome will not be effective in any major way. This has been the actual case in Egypt. The retail market, which caters to the largest demand base, is to date operating without clear policy guidelines with regards generic policy. In the domain of private health care services, where the scope of the associated retail pharmaceutical market stands in excess of LE 13 billion, there is no formal policy regarding promoting generic prescription. Local generic companies have often complained that the relatively large marketing budgets of research-based companies -which are also supported by first-movers advantage in the generics market- work to their disadvantage as these budgets are translated into more frequent visits per physician as well as a larger number of free samples for giveaways, thus influencing prescribing preferences.

The findings also indicate that while the share of generic pharmaceutical products listed on the reimbursement (positive) list of key institutional insurers such as the HIO, as well as for MOH tenders is larger than the share of originator products, the demand base of these two largest institutional consumers of medicine in Egypt remains to be relatively small compared to the overall market.

In 2008, while generics accounted for 50 percent of Egypt's retail market by value, generics substitution in pharmacies is not formally supported from a policy perspective, nor is it common practice in Egypt. While dispensing pharmacists in private pharmacies often

[20] The Bolar Provision (as originated in the USA) refers to the ability of generic manufacturers to proceed with the necessary work, which is meant to assist in obtaining regulatory approval as well as marketing of a product which is still in-patent. This includes reliance on the technology used to manufacture the innovator brand. The Bolar Provision allows generic companies to immediately launch their products once the patent on the concerned product expires.

propose alternatives to products which may not be available, this practice is rarely exercised in a systemic method to relieve patients from paying higher prices for originator/brand-name drugs by proposing generic substitutes.

Limiting the number of identical products in terms of therapeutic value and dosage forms to four, is also one of the key limitations of the regulatory regime as it negatively impacts on increased competition.

With regards requirements for co-payments towards the cost of drugs for the three largest groups of beneficiaries under the umbrella of social health insurance, differential co-payments to promote generic drugs remain to be absent. In other words, generics do not attract lower copayments compared to the branded version of the same medicine.

This chapter provided the necessary context against which the research question concerning relative price levels on Egypt's pharmaceutical market can be addressed. Chapter Six will examine in more detail, and based on real market data, the nature of price competition between various products on Egypt's pharmaceutical market and the extent to which consumers (patients) have been able to capitalize fully on the cost advantage of having access to a large generics medicine manufacturing base.

5. HAVE MECHANISMS USED TO PROTECT AND REGULATE THE EGYPTIAN PHARMACEUTICAL INDUSTRY BEEN ASSOCIATED WITH PRODUCTIVITY GROWTH?

5.1 Introduction

In this chapter, we provide an answer to the research question concerning the extent to which mechanisms used to protect and regulate the Egyptian pharmaceutical industry have been associated with productivity growth will be undertakne.

In order to provide an answer to this question, and after having reviewed the nature of regulatory protectionism in Egypt -as detailed in the two previous chapters- total factor productivity (TFP) growth in Egypt's generics pharmaceutical industry during the period 1993-2005 will be estimated. The non-parametric, frontier methodology known as data envelopment analysis (DEA) to obtain the Malmquist productivity index at the firm-level for a representative sample of firms operating in the Egyptian pharmaceutical industry will be relied upon. The results provided insight to identify the best-practice firm and the laggard firm in the three aspects of: efficiency change, technical change and TFP growth. Efficiency change, technical change and TFP growth are the qualitative productivity improvements needed to achieve long-term economic growth.

Empirical results indicated that the best-practice firm in terms of TFP change belonged to the private sector, while the laggard firm belonged to the state-owned public business sector. No differences of significance exist between the performance of private sector and state-owned generics companies. Additionally, state-owned companies which have been subject to partial privatization did not exhibit higher levels of TFP change compared to those which remained under full state-ownership. Empirical results also indicated that mean TFP change for the sample firms throughout the study period (1.01) exceeded the mean TFP change for all Egyptian industries (0.75), and that there was evident disassociation or week correlation -at best- between productivity growth and the degree of export orientation.

This chapter is structured as follows. Section 5.2 presents the methodology to estimate TFP growth in Egypt's generics pharmaceutical industry. Section 5.3 presents the empirical results, while section 5.4 summarises the key findings and presents the concluding remarks.

5.2 Research Methodology

Research that has relied on longitudinal microdata has traditionally been divided into two key groups. The first group has been concerned with documenting and describing productivity, while the second has been concerned with examining the factors behind productivity growth. The first group endeavoured to document the cross-sectional distribution of productivity and the evolution of productivity growth. This faction of empirical work has presented useful stylized facts regarding the dispersion of productivity "across firms and establishments, productivity differentials and the consequences of entry and exit and the importance of changes in the resource allocation across firms to aggregated productivity growth" (Bartelsman and Doms, 2000). It is to this strand of the literature that this thesis is aligned. The second strand of the literature documented the correlation between productivity and variables believed to influence it. The more analytical faction of the literature takes a step further to answer the relatively more difficult yet highly important question of causality (Bartelsman and Doms, 2000).

5.2.1 Estimation of TFP growth using non-parametric productivity measurements

Methods to estimate TFP growth on an economy-wide level fall in two key classes. The first is growth accounting which has been the standard measurement approach since Solow (1957). In this case, measurement relies on accounting for the contribution of growth in factor inputs to the growth of output. The residual part of output growth, which cannot be accounted for by inputs, is TFP growth (Krüger, 2003). The conventional approach based on the Solow residual method has four basic assumptions 1) that the form of the production function is known; 2) constant returns to scale exist; 3) firms exhibit optimizing behaviour, with no room for inefficiencies and 4) that there is neutral technical change. Once these assumptions do not hold, measurements of TFP will become biased (Coelli et al., 1998; Arcelus and Arocena, 2000). The second method measures TFP growth by estimating frontier production functions "and then derive productivity changes from both the changes

in inputs and outputs …. and the shifts of the frontier function" (Krüger, 2003). These are basically the two techniques to measuring TFP growth. Details regarding the advantages of each methodology is covered in more detail in Mahadevan (2004).

Within the second strand, two conceptually different methods exist. In the first case, the estimation of the frontier function can be done using parametric methods for the stochastic frontier analysis (SFA). The advantage of this method is being able to deal with measurement errors. However, it requires the specification of the functional form of the production function. In addition, specific distributional assumptions are necessary for the separation of the distance to the frontier from measurement error (Krüger, 2003). "The primary shortcomings of parametric frontier estimation techniques are the need to use predetermined functional forms (e.g. Cobb-Douglas, translog, transcendental etc.) and their reliance on pre-specified types of error distribution. In the second case, a non-parametric estimator is a robust estimator that allows the data to determine the shape of the functional form without any constraints derived from relevant economic theory. The advantage of nonparametric estimators is that they do not possess the same limitation as parametric frontier estimation techniques because they do not rely on these same strict assumptions. Among the commonly used non-parametric methods is the DEA" (Haghiri et al, 2004, p. 1235). The development of DEA is attributed to Charnes, Cooper and Rhodes (1978). What DEA does, is that it analyses the inputs and outputs of products/services providers -termed decision-making units- (DMU), and assesses their overall efficiency (Nyhan and Martin, 1999).

This thesis uses a non-parametric, frontier methodology known as DEA to obtain the Malmquist productivity index at the firm-level for a sample of firms operating in the Egyptian pharmaceutical industry. The study period extends between 1993 and 2005. The results will provide insight to identify the best-practice firm and the laggard firm in the three aspects of: efficiency change, technical change and TFP growth. Efficiency change, technical change and TFP growth are the qualitative productivity improvements needed to achieve long-term economic growth.

DEA is a special application of linear programming, and has become an important and much used tool in conducting provider/manufacturer comparisons. The technique of DEA to measure firm-level performance is useful for the comparative evaluation of firm-level efficiency and has been extensively used in the literature (Ahuja and Majumdar, 1998). DEA has been used to make provider comparisons in schools (Callen, 1991; Chalos and Cherian, 1995), to compare human services agencies (Ozcan and Cotter, 1994), court systems (Lewin, Morey and Cook, 1982) as well as the quality of health care providers (Capettini, Dittman and Morey, 1985). By making such comparisons, the expectation is that the best-practice manufacturers can be identified and then used as the benchmarks for improving the efficiency and quality of similar activities (Nyhan and Martin, 1999: 349). Within the framework of DEA, the location of the frontier relative to each of the observed firms/providers is constructed as an artificial benchmark firm. This benchmark is the linear combination of efficient firms in a possibly different sample (Berg, Førsund and Jansen, 1992: S218).

While both efficiency change as well as technical change will be examined, emphasis will be placed on TFP. It is important to note that TFP is evaluated to be theoretically superior as an indicator of technical efficiency than any other partial factor measure of productivity including labour productivity, because it measures the productivity of all inputs used in the production process jointly (Keay, 2000).

5.2.2 Advantage of using DEA

The advantage of using DEA is that it provides significant flexibilities in terms of data selection. Inputs and outputs can be continuous, ordinal or categorical variables, and can be measured in different units of analysis such as dollars, score tests, hiring rates or units of output. Output within the context of DEA can be broadly interpreted to include not only output performance measures, but also quality performance measures and outcome performance measures. Similarly, the term efficiency can be interpreted to include not only the assessment of efficiency, but also an assessment of both quality and effectiveness. In other words, outcome. DEA can, therefore, make assessments of efficiency, quality,

effectiveness or any combination thereof. DEA has three key advantages over simple ratio analysis as well as regression analysis:

> "First, DEA assigns mathematically optimal weights to all inputs and outputs being considered, whereas ratio analysis and regression analysis rely on the preferences of policymakers and policy evaluations in the assigning of weights. Because DEA is a non-parametric technique, no need exists for the a priori assignment of weights. …Second, DEA can make simultaneous comparisons of multiple dependent performance measures (output, quality, and outcome) and can provide a scalar measure of best overall practice, a feature that neither simple ratio analysis nor regression analysis can duplicate. …. Thirdly. DEA can calculate the amount of resources that can be saved or, conversely, the amount of additional output, quality, or outcome that can be produced for any provider found to be inefficient" (Nyhan and Martin, 1999:354-355).

In the case of the nonparametric approach of DEA, the deviation of observations from the frontier function is taken as a result of inefficiency. Measurement error is neglected and results are made more sensitive to outliers. Using linear programming methods, the advantage of DEA (against SFA) is that the frontier function is determined without any functional or distributional assumptions. "DEA is a local method in that it calculates the distance to frontier function through a direct comparison with only those observed in the sample that are most similar to the observations for which the inefficiency is to be determined" (Krüger, 2003: 267)

5.2.3 Limitations of DEA

To begin with, DEA is not a 'panacea' for making service/manufacturer provider comparisons as technical as well as practical limitations exist. The mathematical complexity of DEA represents one of the hurdles that need to be overcome, as it may turn out to be too technical for practical usage. DEA specific software applications have helped to 'deemphasize' the mathematics of the analysis, while at the same time increasing the conceptual understanding and practical value as a decision-making tool for policy makers as well as policy evaluators. By virtue of being a nonparametric technique, DEA has no statistical indicators to measure error (noise) as does regression. In general, nonparametric techniques are not appropriate for hypothesis testing. In light of such limitations, researchers using DEA must be well grounded in their data. The number of providers to be

included in a DEA is also one of the important technical considerations. There is a need for between 4 and 15 observations for each independent variable included in a regression for DEA. Studies which use small numbers of decision making unites (DMUs) may risk being potentially biased, whereas studies using large numbers of DMUs do add to the robustness of the DEA solutions. An important note, which also needs to be taken into considerations, is that because DEA uses relative comparisons, it is possible that all DMUs in a study could be inefficient, but with some being relatively less inefficient. Another important consideration is related to the number of input and performance variables included in a DEA. Using large numbers of input and performance variables in an "exploratory data analysis" approach may be considered as methodologically unsound. Parsimonious numbers of input and performance variables tend to actually have greater explanatory value. One of the characteristics of DEA is that as more input and performance variables are included in the analysis, the proportion of efficient or best practice firms tends to increase (Nyhan and Martin, 1999:360-361).

An important consideration is also related to one potentially significant issue ignored in the application of the Malmquist productivity index, which is related to the possibility that changes in technical efficiency may be *partially* explained by changes in the utilization of production capacity (De Borger and Kerstens, 2000: 304).

5.2.4 The Malmquist Index

Regardless of the methods used to calculate distances, growth of TFP is then quantified by the Malmquist index. DEA generates an efficiency score for each DMU, relative to a reference technology based on the sample of efficient firms. In order to identify productivity growth in a firm between two time periods, the Malmquist productivity index is used. The Malmquist index has been introduced by Malmquist (1953) in a consumption context and by Caves et al. (1982) as a productivity index, and has been extensively referred to in the literature (Krüger, 2003: 267). The Malmquist productivity index is defined as a ratio of distance functions. Fare et al. (1995) developed a straightforward computational procedure to calculate the index relative to nonparametric frontier technologies by means of using the inverse relationship between output distance functions

and output-oriented technical efficiency measures. Fare et al. (1995) also demonstrated that the Malmquist productivity index can be decomposed into technical efficiency changes and technological shifts (De Borger and Kerstens, 2000: 303).

The Malmquist index remains to be a valuable tool in terms of allowing for the decomposition of productivity into two important components, namely innovation and imitation. The first component which is innovation, is also called technological change, and it captures any expansion of the production possibilities frontier. The second component, which is called imitation, captures the convergence of firms in the direction of the existing technology. This phenomenon is called efficiency change or "catching up" (Alam, 2001).

The following section presents the essential of procedures to obtain the Malmquist index of TFP growth, as detailed in Krüger (2003).

Essentials of the procedures to obtain the Malmquist Index of TFP

The Malmquist index of TFP growth *M* between period t and period t+1 is stated as follows:

$$M_h^{t+1}(\chi_h^t, y_h^t, \chi_h^{t+1}, y_h^{t+1}) = \left[\frac{D_h^t(\chi_h^{t+1}, y_h^{t+1}) D_h^{t+1}(\chi_h^{t+1}, y_h^{t+1})}{D_h^t(\chi_h^t, y_h^t) D_h^{t+1}(\chi_h^t, y_h^t)} \right]^{1/2} \quad (1)$$

The two inputs (in the case of this thesis there are three inputs) capital *K* and labour *L* of firm *h* (*h*=1, …,*n*) in period *t* are contained in the input vector $x^t_h = (K_{ht}, L_{ht})'$ and the sector wide output *Y* is replicated $Y^t_h = (Y_{ht})$. The Malmquist index is the geometric mean of two ratios of distance functions of the type

$$D_h^P(x_h^q, y_h^q) = (\sup\{\phi : (x_h^q, \phi y_h^q) \in S(p)\})^{-1} ; p,q = t,t+1 \quad (2)$$

this gives the reciprocal of the maximum augmentation of output in period *q* that is needed to reach the boundary point of the technology set

$$S(p) = \{(x_h^p, y_h^p) : x_h^p \geq 0 \text{ can produce } y_h^p \geq 0, \forall h = 1,\ldots, n\} \quad (3)$$

in period *p*. The Malmquist index will then indicate positive (negative) TFP growth between period t and *t*+1 if it is larger (smaller) than 1.

The Malmquist index can be decomposed into two factors of importance

$$M_h^{t+1} = (x_h^t, y_h^t, x_h^{t+1}, y_h^{t+1}) = \underbrace{\frac{D_h^{t+1}(x_h^{t+1}, y_h^{t+1})}{D_h^t(x_h^t, y_h^t)}}_{EF_h^{t+1}} \underbrace{\left[\frac{D_h^t(x_h^{t+1}, y_h^{t+1})}{D_h^{t+1}(x_h^{t+1}, y_h^{t+1})} \frac{D_h^t(x_h^t, y_h^t)}{D_h^{t+1}(x_h^t, y_h^t)}\right]^{1/2}}_{TP_h^{t+1}} \quad (4)$$

In which the first factor EF denotes the change in productive efficiency between period *t* and *t*+1, while the second factor TP denotes the rate of technological change (Krüger, 2003).

Using real data, the application of the above theoretical device for inputs and output a method for the quantification of the various distance functions (2) is required. Such calculations are performed by solving the linear programming problems of DEA. In this chapter the output-oriented envelopment for firm *h* (assuming constant returns to scale)

$$\max_{\varphi,\lambda} \varphi_h$$

$$\text{s.t. } \phi_h Y_{hq} - \sum_{i=1}^{n} \lambda_i Y_{ip} \leq 0$$

$$\sum_{i=1}^{n} \lambda_i K_{ip} \leq K_{hq}$$

$$\sum_{i=1}^{n} \lambda_i L_{ip} \leq L_{hq}$$

$$\lambda_1, \ldots\ldots, \lambda_n \geq 0 \quad (5)$$

and then setting $D_h^p\ (x_h^q, y_h^q) = \phi_h^{-1}$ for all (p,q) Є {(t,t), (t,t+1),(t+1,t), (t+1,t+1)}.

According to this procedure, the input-output combinations each firm in period q is compared to the piece-wise linear frontier production function which consists of the input-output combinations of the most productive firms in period q. The maximization increases ϕ_h. Each firm in period q is compared to a point on the frontier function that is constructed by the λ-weighted linear combination on the inputs and outputs of the all firms in period p, whereby only the firms that are most similar to h are assigned a positive value to λ (Krüger, 2003).

The software DEAP, which has been developed by Coelli (1996), has been used to compute the indices.

5.2.5 Data Sources

Data needed for the application of the Malmquist-DEA procedure was obtained directly from the sample firms for the period 1993-2005. Three inputs have been used, namely labour, intermediate inputs and capital. Labour input has been quantified by the number of workers. Intermediate inputs included raw material (local+ imported), packaging material, gas, electricity and spare parts. Capital input is based on the value of the capital stock. As to the output variable, output value (in current prices) for each firm was used.

Several price indices have been resorted to in order to deflate output, intermediate inputs and capital stock values. The investment deflator has been obtained from the Ministry of Planning, and has been used to deflate the value of the capital stock. The various components of the wholesale price index (WPI) have been relied on to deflate intermediate input values. The consumer price index (CPI) has been used to deflate output values (Annexes 5, 6 and 7).

Sample companies

Initially, all companies which have started production during the first year of the study period or earlier have been approached for inclusion in the sample. However, some companies chose not to cooperate, whereby a total of 13 companies out of the pool of 16 generic companies which were operative throughout the study period were included in the sample (see Annex 8 for a full list of companies in Egypt and first year in operation). The main reason for not including companies which began actual production after 1993 was that there was a need for having continuous availability of data for a common sample. The approach to sample selection has been based on nonprobability sampling. Nonprobability sampling which is based on "convenience", whereby cases are being selected based on their availability for the study. A limitation of nonprobability samples is, however, that there is an element of uncertainty when the sample is used to represent the population. As such the selection procedure does not provide rules or methods to infer sample results to the population in contrast to probability sampling (Henry, 1990). Nonprobability sampling was, nonetheless, the only method to obtain data in the situation of this thesis. Moreover, the fact that 13 out of the total of 16 companies (the whole population of companies which began actual production during the early 1990s) reduced the level of uncertainty and bias.

Of the 13 generics pharmaceutical companies subject to study, 8 companies are majority owned by the state, of which 5 have been subject to partial privatization under the umbrella of the 1991 ERSAP. A few of these state-owned companies exhibit higher exports-to-output ratios compared to the others. Hence for this group of companies, productivity trends can be linked to their privatization status, as well as to export performance.

Locally owned private sector companies also reflect a set of differences. Some companies are of older age in terms of years of operation. In addition, some of the sample companies export as much as 15 percent of total output, while others export as little as three percent.

EIPICO holds the largest share of the pharmaceutical market, which stood at 9.4 percent in 2008, while PHARCO is the lead firm in terms of exports as a percent of output value at

14.7 percent. Only one of the private sector companies, namely SEDICO, has a large foreign equity share which stands at 34 percent of issued capital (GAFI, 2009).

Table 5-1: Sample characteristics

Company name	Establishment Date	Production	Issued Capital LE '000	Ownership	Market Share 2008 (by value) %	Exports % of output 2006
Misr	1937	n.a.	n.a.	Public sector	1.3	14.6
Memphis	1940	n.a.	n.a.	Public sector	2.0	8.5
CID	1950	n.a.	n.a.	Public sector	2.5	3.0
Alex	1963	n.a.	n.a.	Public sector	1.3	7.7
Kahira	1963	n.a.	n.a.	Public sector	3.6	12.0
Nile	1963	n.a.	n.a.	Public sector	2.4	8.6
ADCO	1964	n.a.	n.a.	Public sector	1.5	5.7
Nasr	1964	n.a.	n.a.	Public sector	0.4	8.5
EIPICO	1980	1985	n.a.	Private	9.4	14.5
PHARCO	1982	1987	500,000	Private	7.9	14.7
SEDICO	1983	1990	223,768	Private	2.6	12.6
Amirya	1984	1988	216,000	Private	2.6	7.4
MUP	1984	1989	313,387	Private	7.3	7.3

Sources: Drug Holding Company, 1992a; General Authority for Investment and Free Zones, 2009; IMS Health, 2009; Handoussa, 1974

In 2008, and based on IMS data, the 13 sample companies were among the largest players on the local market, having accounted for 62 percent of the generics market in Egypt by volume and 45 percent by value (Table 5-2).

Apart from differences related to the date of establishment, ownership structure, market shares, export-to-output ratios and installed productive capacity, all of the sample companies are considered to be highly similar in light of the fact that they engage in generic formulation activities. Like all generic companies in Egypt, no pharmaceutical R&D activities are undertaken by the sample companies.

Annex Table 9 provides the full data which portrays relative output levels of the sample companies, size of the workforce and capital stock during the study period.

Table 5-2: Market share of the 13 sample companies 2004-2008

	Units ('000)					LE Sales ('000)				
	2004	**2005**	**2006**	**2007**	**2008**	**2004**	**2005**	**2006**	**2007**	**2008**
Total pharmaceutical market	**873,498**	**1,013,349**	**1,105,487**	**1,209,421**	**1,323,496**	**6,279,026**	**7,864,763**	**9,319,250**	**10,954,963**	**12,565,859**
Generics market	**650,367**	**786,654**	**867,524**	**953,950**	**1,043,137**	**4,079,421**	**5,331,087**	**6,322,684**	**7,546,539**	**8,686,921**
Public sector sample companies share of the generics market (%)										
ADCO	3.0	2.5	2.1	1.9	1.9	2.2	1.9	1.7	1.5	1.5
ALEX	3.5	3.5	3.3	2.5	2.2	2.3	2.2	2.0	1.5	1.3
CID	6.9	6.5	5.8	5.7	5.3	4.0	3.5	3.0	2.8	2.5
KAHIRA	6.0	5.1	4.9	4.5	4.2	4.4	4.2	4.0	3.8	3.6
MEMPHIS	4.2	3.9	3.5	3.2	3.0	3.3	3.0	2.6	2.3	2.0
MISR	4.4	3.8	3.3	2.8	2.7	2.1	1.8	1.5	1.4	1.3
NASR	1.5	1.3	0.8	0.7	0.7	1.1	0.9	0.5	0.4	0.4
NILE	5.1	4.2	4.0	3.7	3.3	3.5	3.1	2.8	2.6	2.4
Private sector sample companies share of the generics market (%)										
AMRIYA	6.6	5.9	3.4	3.3	3.9	5.5	4.7	2.5	2.3	2.6
EIPICO	10.9	12.2	14.1	13.6	13.0	8.2	8.9	10.0	9.7	9.4
MUP	8.2	7.9	7.6	7.8	8.1	8.9	8.3	7.8	7.6	7.3
PHARCO	11.5	11.3	11.2	11.0	11.3	8.8	8.6	8.4	7.9	7.9
SEDICO	2.8	2.2	2.5	2.8	2.1	3.9	3.2	3.5	3.5	2.6
Sample % generics market	**74.4**	**70.4**	**66.5**	**63.5**	**61.6**	**58.3**	**54.3**	**50.4**	**47.4**	**44.6**

Source: IMS, 2009

The estimation of productivity for the sample companies will allow for several layers of analysis. With regards ownership, the estimation of productivity growth of firms in the public sector versus the private sector will be conducted. In addition, the estimation of productivity growth exhibited by public sector firms subject to partial privatization, versus firms which remained under full state ownership will also be undertaken. The productivity of all local firms in the public and private sector will also be estimated against the criteria of output-to-export ratios.

5.3 Empirical Results

This section summarizes the results which have been obtained through DEA by calculating the required distances functions using the DEAP programme developed by Coelli (1996). For the *i*th firm, four distance functions to measure the TFP change between two periods has been calculated. This required solving four linear programming (LP) problems (four for each firm of the sample).The pool of data required for the calculation of the MPI has been detailed earlier in this chapter.

Looking at the empirical results, an index of one represents no change in productivity growth from the previous to the current period. In any year, an index of 0.90 represents a decline of 10 percent in productivity growth, while an index of 1.01 would represent an increase of one percent in productivity growth.

5.3.1 Time series technical efficiency change (catching-up)

Table 5-3 presents the scores for average efficiency change for all sample firms during the 13-year study period. The years 1995 and 2000 recorded the largest effects on efficiency change. The Malmquist index summary of annual means indicated positive technical efficiency change (relative to constant returns to scale) in 7 out of the 13-year study period.

Table 5-3: Malmquist index summary of annual means

year	Technical efficiency change (relative to a CRS technology)	Technological change	Pure technical efficiency change (relative to VRS technology)	Scale efficiency change	Total Factor Productivity Change
1994	0.693	1.544	0.821	0.844	1.071
1995	1.426	0.743	1.267	1.126	1.060
1996	1.036	0.911	1.004	1.032	0.944
1997	1.018	1.007	1.016	1.003	1.026
1998	0.963	1.037	0.982	0.981	0.999
1999	1.028	0.985	0.995	1.033	1.012
2000	1.046	0.958	1.046	1.000	1.002
2001	1.017	0.978	1.023	0.994	0.995
2002	0.995	0.983	0.977	1.018	0.978
2003	1.025	0.977	1.014	1.011	1.001
2004	0.950	1.009	0.957	0.993	0.959
2005	0.962	1.101	0.976	0.986	1.059
mean	1.002	1.006	1.002	1.000	1.008

5.3.2 Time series technological efficiency change (innovation)

Empirical evidence indicated that for the sample firms, there has been limited scope for innovation. Table 5-3 indicates that the highest scores for technological change occurred in 1994, in 1998, and then as late as 2005. Most of the private sector sample firms have commenced actual production during the late 1980s, with the early years of the 1990s witnessing the expansion in their productive capacity. During the second half of the 1990s, and particularly with the uncertainty associated with what was judged to be a relatively detrimental impact of the TRIPS Agreement on the future of the local generics industry, most of the private sector companies in Egypt were in a situation which entailed conservative investments in new state-of-the art capital goods. In addition, during the second half of the 1990s and up to January 2003, Egypt has been facing significant foreign exchange shortages, which has hampered the ability of local companies to import and deploy new generations of technology.

Local generics companies have also been particularly sensitive to exchange rate fluctuations, as they import close to 90 percent of their intermediate raw material inputs, and have been rarely able to accommodate exchange rate movements in terms of price adjustments. It was largely argued within industry circles that the implications for profitability levels have been significant, which in turn affected the ability to modernize their capital stock as well as to invest in state of the art generations of technology necessary to impact positively on technological efficiency change.

Because public business sector companies account for the largest number of firms in the sample of companies, results are likely to be sensitive to the overall performance of these companies. On the technological efficiency front, public business sector companies have been facing serious profitability problems (in association with pricing) and have not been able to invest appropriately in technological upgrading. CID, Al-Kahira and Misr have been judged to be technically incapable of surviving with the deteriorating condition of their capital stock (Interview, Dr. Galal Ghorab, Director, Drug Holding Company, April, 2004). For example, and as mentioned earlier, regular inspections conducted by the Ministry of Health (in 1999 and 2000) cautioned that the manufacturing facilities of the Arab Drug Company (ADCO) were in dire need for rehabilitation, otherwise the companies facilities would be subjected to closure. The reason is that some of ADCO's machinery, which date back to 1963, were still in operation. Foreign licensors have been threatening ADCO in particular to withdraw their licenses, unless the rehabilitation and modernization of the company's manufacturing facilities were to be addressed (ADCO, 2003).

5.3.3 Time series TFP change

Table 5-3 also indicates that during the study period, mean TFP change for the entire sample of firms was relatively favourable in terms of exceeding the threshold of an index of 1. This is particularly true if compared to the overall performance of Egyptian manufacturing industries (Annex Table 10). Mean TFP change throughout the study period (1.01) exceeded mean TFP change for all Egyptian industries (0.75) during the period 1980/80-2000/01 (Galal, Ahmed and El-Megharbel, 2005). Taking into consideration that this industry has been thriving behind significant regulatory non-tariff barriers, TFP change

has been generally positive, with only 5 out of the 13-year study period registering productivity regress.

5.3.4 Firm-level technical efficiency change

One important observation concerning firm-level technical efficiency change (Table 5-4) is that three of the private sector companies, namely Amriya, PHARCO and MUP have experienced no change in technical efficiency during much of the study period. The three firms are in fact among the oldest in terms of year of establishment and also among the key players on the market by virtue of market shares. The remaining two private sector companies in the sample -EIPICO and SEDICO- have experienced fluctuations in technical efficiency change, with a non-consistent pattern moving from the positive to the negative throughout the study period. Public business sector companies have also shared the same pattern.

Table 5-4: Firm level technical efficiency change (relative to a CRS technology)

	94	95	96	97	98	99	00	01	02	03	04	05
ADCO*	0.69	1.44	1.11	1.04	0.95	0.91	1.29	1.07	1.00	1.00	0.91	0.88
Alex*	0.63	1.38	1.04	1.09	0.96	0.98	1.08	1.03	0.97	1.08	0.84	0.92
Amirya	0.76	1.31	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
CID*	0.47	1.98	1.03	1.03	1.02	1.08	1.15	1.00	0.99	0.90	0.94	0.83
EIPICO	1.00	1.00	0.98	1.00	0.89	1.12	0.86	0.96	1.09	1.04	1.05	0.93
Kahira*	0.77	1.39	1.01	1.02	0.89	0.97	1.03	0.99	0.97	1.05	0.98	0.87
Memphi	0.55	1.63	0.99	1.15	0.97	1.04	1.01	0.97	1.05	1.03	0.87	0.97
Misr*	0.59	1.59	1.15	1.11	0.97	0.97	1.29	0.99	1.01	0.92	1.06	0.97
MUP	1.05	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Nasr*	0.39	3.06	1.14	0.79	0.80	1.21	0.98	1.23	0.92	1.02	0.98	0.96
Nile*	0.51	1.72	1.04	1.02	1.03	1.04	0.99	1.04	0.93	1.13	0.74	1.26
PHARC	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
SEDIC	0.99	1.00	0.95	0.98	1.03	1.02	0.95	0.92	0.97	1.15	1.00	0.94
Mean	0.69	1.42	1.03	1.01	0.96	1.02	1.04	1.01	0.99	1.02	0.95	0.96

** Public Business Sector Companies*

5.3.5 Firm level Technological change

Table 5-5 indicates that 1994 and 1998 have been two years of significance for technological change for all sample firms. MUP has been the lead firm in terms of consistency in positive technological change in 9 of the 13-year study period (see Table 5-

8). There are no significant differences between public and private sector firms in terms of achievements on the technological change front. Overall, the results indicate a weaker performance on the innovation front by all companies in the sample.

Table 5-5: Firm level technological change

	94	95	96	97	98	99	00	01	02	03	04	05
ADCO	1.63	0.63	0.89	1.02	1.04	1.00	0.81	1.01	0.98	0.98	1.02	1.16
Alex	1.59	0.73	0.88	0.99	1.02	0.99	0.98	0.90	1.02	0.97	1.01	1.13
Amriya	1.51	0.80	0.95	0.96	1.05	0.98	1.07	1.05	0.94	0.91	1.02	0.89
CID	1.97	0.59	0.87	0.99	1.03	0.99	0.93	0.97	0.99	0.98	1.04	1.14
EIPICO	1.56	0.77	0.81	1.03	1.06	1.00	1.02	0.94	1.00	0.94	0.96	1.15
Kahira	1.41	0.72	0.89	1.02	1.05	1.00	0.98	0.96	0.99	0.97	1.02	1.10
Memphi	1.93	0.64	0.92	0.95	1.00	0.99	1.01	1.00	0.95	0.95	1.03	1.05
Misr	1.82	0.58	0.87	1.00	1.03	1.00	0.96	0.96	1.00	0.96	1.02	1.11
MUP	1.22	1.13	1.07	1.06	1.02	0.86	1.06	0.98	1.03	1.03	0.87	1.27
Nasr	1.84	0.64	1.04	0.96	1.00	0.99	1.03	1.10	0.92	0.93	1.04	0.99
Nile	1.68	0.58	0.87	0.97	1.01	0.99	0.99	0.96	0.98	0.95	1.00	0.98
PHARC	1.08	1.10	0.77	1.03	1.10	1.01	0.63	0.91	0.95	1.18	1.15	1.21
SEDIC	1.13	0.94	1.02	1.06	1.03	0.96	1.04	0.94	1.00	0.92	0.91	1.13
mean	1.54	0.74	0.91	1.00	1.03	0.98	0.95	0.97	0.98	0.97	1.00	1.10

5.3.6 Firm level TFP Change

Table 5-6 indicates that MUP emerged as the best practice firm in terms of positive TFP change. No difference of significance mark TFP change between public and private sector firms. TFP change exhibited by public business sector firms which have been subject to partial privatization did not differ much from those which remained under full state ownership. In fact Misr, which is under full state ownership, achieved consistently positive TFP change compared to an all other of the public business sector companies. Foreign participation in equity (SEDICO) did not seem to have had an impact of significance on TFP change.

Table 5-6: Firm level TFP change

	94	95	96	97	98	99	00	200	02	03	04	05
ADCO	1.13	0.91	0.99	1.06	0.99	0.91	1.05	1.09	0.98	0.98	0.93	1.02
Alex	1.01	1.01	0.92	1.08	0.99	0.98	1.06	0.93	0.99	1.05	0.85	1.04
Amirya	1.15	1.05	0.95	0.96	1.05	0.98	1.07	1.05	0.94	0.91	1.02	0.89
CID	0.93	1.18	0.90	1.03	1.05	1.08	1.08	0.97	0.99	0.89	0.98	0.95
EIPICO	1.56	0.77	0.80	1.04	0.95	1.12	0.88	0.91	1.09	0.98	1.01	1.07
Kahira	1.09	1.00	0.90	1.05	0.94	0.98	1.02	0.95	0.96	1.02	1.01	0.97
Memphi	1.06	1.05	0.91	1.09	0.97	1.03	1.03	0.97	0.99	0.98	0.89	1.02
Misr	1.08	0.93	1.01	1.12	1.01	0.97	1.25	0.95	1.01	0.88	1.09	1.08
MUP	1.29	1.13	1.07	1.06	1.02	0.86	1.06	0.98	1.03	1.03	0.87	1.27
Nasr	0.72	1.97	1.19	0.76	0.80	1.20	1.02	1.36	0.86	0.96	1.03	0.95
Nile	0.87	1.01	0.91	0.99	1.04	1.03	0.99	1.01	0.91	1.08	0.74	1.24
PHARC	1.08	1.10	0.77	1.03	1.1	1.01	0.63	0.91	0.95	1.18	1.15	1.21
SEDIC	1.12	0.95	0.97	1.05	1.07	0.98	0.99	0.86	0.97	1.06	0.91	1.07
mean	1.07	1.06	0.94	1.02	0.99	1.01	1.00	0.99	0.97	1.00	0.95	1.05

Table 5-7 indicates that the dominant effect for the sample firms has been TFP change.

Table 5-7: Malmquist index summary of firm means

	Technical efficiency change (relative to a CRS technology)	Technological change	Pure technical efficiency change (relative to VRS technology)	Scale efficiency change	Total Factor Productivity Change
ADCO	1.011	0.995	1.026	0.986	1.006
Alex	0.990	1.006	0.990	1.000	0.996
Amriya	1.000	1.003	1.000	1.000	1.003
CID	0.992	1.011	0.988	1.004	1.003
EIPICO	0.995	1.009	1.000	0.995	1.004
Kahira	0.992	1.002	0.991	1.001	0.994
Memphis	0.997	1.007	0.994	1.003	1.004
Misr	1.031	1.000	1.034	0.996	1.031
MUP	1.005	1.049	1.002	1.003	1.053
Nasr	1.014	1.017	1.004	1.010	1.031
Nile	1.005	0.977	1.001	1.004	0.982
PHARCO	1.000	0.999	1.000	1.000	0.999
SEDICO	0.995	1.007	1.000	0.995	1.002
mean	1.002	1.006	1.002	1.000	1.008

All Malmquist index averages are geometric means

Table 5-8 indicates that MUP is the top ranking firm in the sample, as indicated by the number of times it has ranked as having positive TFP change. MUP is also the top ranking company as indicated by the number of times it has ranked as technically efficient. While, MUP has been one of the most dynamic and reputable of generic firms in Egypt by virtue of market share, it has been consistently losing market share (as reflected in Table 5-2). ADCO and CID which are public business sector companies, as well as SEDICO (private) rank least in terms of the number of times they scored positive TFP change during the study period. The problems of the public business sector have been alluded to earlier. The categorisation of SEDICO among the least performing companies, however, raises concern as it has been one of the dynamic generics companies on the Egyptian market for pharmaceuticals, with active presence on export markets.

Table 5-8: Number of times sample companies ranked as efficient between 1992-05

	Total factor productivity change	Technical efficiency change (relative to a CRS technology)	Technological change
MUP	9	12	9
Misr	8	6	7
PHARCO	8	12	8
Alex	6	6	5
Amirya	6	11	5
EIPICO	6	7	4
Kahira	6	5	6
Memphis	6	6	6
Nasr	6	5	6
Nile	6	8	3
ADCO	5	7	7
CID	5	7	4
SEDICO	5	5	7

Table 5-9 indicates that the levels of efficiency of individual firms are not dependent on the growth strategy adopted by these firms. The correlation coefficients for the variables output growth and technical efficiency change; technological change and TFP change during the study period 1993-2005 indicates that they have not been moving in the same direction. The exception has been for the two public sector companies Memphis and CID.

Table 5-9: Correlation between efficiency levels and growth strategy for sample firms

	Average growth rate of output 1993-2005	Correlation coefficient for output growth and		
		Technical efficiency change (relative to a CRS technology)	Technological change	TFP Change
PHARCO	16.7	n.a.	0.20	0.20
MUP	12.4	0.40	0.37	0.40
Nasr	10.8	0.03	0.13	-0.09
Nile	8.0	-0.46	0.56	-0.13
SEDICO	5.2	0.05	-0.20	-0.14
EIPICO	4.3	-0.02	-0.74	-0.72
Misr	3.6	-0.52	0.61	0.20
ADCO	3.2	0.37	-0.23	-0.14
CID	2.2	0.49	-0.12	0.68
Memphis	2.2	0.21	0.16	0.83
Kahira	1.4	-0.30	0.36	0.18
Amirya	0.6	-0.33	0.04	-0.31
Alex	0.5	0.05	0.21	0.56

5.3.7 Export-orientation and productivity growth

Table 5-10 indicates evident disassociation or very weak correlation -at best- between productivity growth and the degree of export orientation. Firms that exported a larger share of output were not necessarily gaining on the efficiency front compared to those exporting relatively smaller shares. The opposite is also true. Firms which were not exporting much of their output, were not necessarily less efficient than their opposites.

Table 5-10: TFP Change and export orientation

	ADCO		Alex		Amriya		CID		EIPICO		Kahira		Memphis	
	TFP Δ	Exports*	TFP Δ	Exports	TFP Δ	Exports	TFP Δ	Exports	TFP Δ	Exports	TFP Δ	Exports	TFP Δ	Exports
1994	1.132	3.9	1.012	4.2	1.150	1.2	0.937	4.1	1.569	10.2	1.093	6.4	1.065	5.1
1995	0.917	5.5	1.011	4.1	1.053	1.3	1.186	2.3	0.779	11.9	1.005	6.6	1.055	4.6
1996	0.996	7.2	0.922	5.5	0.952	2.7	0.902	0.7	0.802	10.6	0.909	5.6	0.917	5.7
1997	1.064	5.4	1.086	3.7	0.967	2.4	1.033	2.9	1.041	9.5	1.059	7.5	1.097	5.1
1998	0.997	6.9	0.997	4.2	1.056	2.6	1.056	3.9	0.952	13.8	0.945	13.9	0.975	5.0
1999	0.915	10.8	0.986	4.9	0.980	2.6	1.084	3.3	1.129	11.4	0.980	13.7	1.038	5.3
2000	1.051	7.8	1.065	4.0	1.079	1.6	1.080	2.0	0.885	10.7	1.024	10.5	1.033	1.9
2001	1.098	6.6	0.939	4.0	1.051	2.5	0.976	2.2	0.911	11.9	0.958	12.0	0.977	4.5
2002	0.982	7.8	0.990	4.5	0.949	2.8	0.995	2.6	1.091	12.1	0.967	14.3	0.999	5.1
2003	0.985	13.3	1.058	5.5	0.918	5.8	0.890	3.9	0.987	12.7	1.022	11.5	0.982	3.6
2004	0.935	18.1	0.859	6.8	1.024	4.1	0.986	4.5	1.017	12.3	1.013	13.3	0.897	6.9
2005	1.024	6.0	1.049	7.1	0.893	9.0	0.955	4.7	1.079	12.7	0.970	11.2	1.029	8.8
Correlation Coefficient		-0.56		-0.34		-0.73		-0.14		-0.25		-0.29		-0.19

	Misr		MUP		Nasr		Nile		PHARCO		SEDICO	
	TFP Δ	Exports	TFP Δ	Exports	TFP Δ	Exports	TFP Δ	Exports	TFP Δ	Exports	TFP Δ	Exports
1994	1.080	9.7	1.292	1.2	0.723	7.1	0.872	9.1	1.089	7.5	1.122	0.2
1995	0.931	9.0	1.138	0.8	1.978	8.1	1.015	9.3	1.106	10.4	0.952	0.5
1996	1.013	10.8	1.070	2.6	1.197	4.2	0.917	8.5	0.778	14.7	0.971	1.4
1997	1.125	13.5	1.068	2.6	0.766	4.1	0.992	7.2	1.038	12.6	1.053	0.6
1998	1.011	14.1	1.020	3.4	0.801	3.8	1.045	7.9	1.100	13.1	1.070	2.0
1999	0.978	15.4	0.867	3.5	1.201	4.7	1.037	9.7	1.015	12.6	0.988	3.6
2000	1.250	5.0	1.064	3.4	1.021	5.2	0.991	8.1	0.630	9.3	0.998	3.7
2001	0.957	8.6	0.984	4.4	1.367	5.7	1.016	9.6	0.912	13.2	0.869	6.0
2002	1.016	11.3	1.034	5.0	0.862	9.0	0.916	13.1	0.954	17.8	0.979	6.3
2003	0.884	13.6	1.039	0.7	0.963	8.6	1.083	16.1	1.186	18.9	1.063	8.0
2004	1.092	13.2	0.874	7.0	1.033	9.5	0.743	15.5	1.151	19.5	0.916	4.8
2005	1.083	12.3	1.279	6.7	0.954	8.8	1.244	11.1	1.212	15.5	1.075	12.8
Correlation Coefficient		-0.39		-0.25		0.11		-0.17		0.34		0.00

*Exports as a share of total output

5.4 Summary and Conclusion

In this chapter, an attempt to address the research question concerning the extent to which mechanisms used to protect and regulate the Egyptian pharmaceutical industry have been associated with productivity growth was undertaken.

To provide an answer to this question, TFP growth in Egypt's generics pharmaceutical industry during the period 1993-2005 for a sample of 13 firms has been estimated. The non-parametric frontier methodology known as data envelopment analysis (DEA) to obtain the Malmquist productivity index at the firm-level for a representative sample of firms operating in the Egyptian pharmaceutical industry was relied upon.

Empirical results indicated that the best-practice firm in terms of TFP change belonged to the private sector, while the laggard firm belonged to the state-owned public business sector as well as the private sector. No differences of significance exist between the performance of private sector and state-owned generics companies. Additionally, state-owned companies which have been subject to partial privatization did not exhibit higher levels of TFP change compared to those which remained under full state-ownership. Empirical results also indicated that mean TFP change for the sample firms throughout the study period (1.01) exceeded the mean TFP change for all Egyptian industries (0.75), and that there was evident disassociation or weak correlation -at best- between productivity growth and the degree of export orientation.

While there has been empirical evidence regarding positive TFP growth in Egypt's pharmaceutical industry (sample firms), under the -relatively protectionist- ruling trade and regulatory regime which has historically kept generics import competition at bay, this should not be generally judged to be a healthy phenomenon. Protectionism may have supported this industry to survive during its formative years, especially since there has been ample historical proof of the inequality and possibly detrimental competition with foreign companies during the 1930s (Handoussa, 1974). Had Egyptian policy makers supported a free trade regime, and eliminated non-tariff regulatory trade barriers in the domain of the

pharmaceutical sector beyond the 1930s, it is most likely that Egypt would not have had a local pharmaceutical industry of the magnitude which is currently present.

While efficiency levels seem to be respectable compared to Egypt's manufacturing sector at large, protracted non-tariff regulatory barriers to trade in the domain of the generics pharmaceutical industry in Egypt have ran parallel to prolonging its inward orientation. The important question which accordingly came to mind has been related to why has an industry which was basically efficient compared to other sectors of manufacturing activity in Egypt not been exploiting export markets to further support growth in output and profitability. The probable answer will be presented in Chapter Six. Chapter Six provided evidence of atypical above average generics-to-originator prices for a selected sample of molecules which account for 4.4 percent of Egypt's pharmaceutical market. Weak generic import competition during most of the history of this industry has created an environment in which local manufacturers of generics were able to cluster their prices around the prices of the originator brands or the price of the first market entrants. If this industry is successfully able to charge atypical prices compared to standard generic-to-originator price ratios prevalent in other world markets, then venturing on the tough track of exporting becomes less attractive. Pharmaceutical exports are made cumbersome due to the high registration fees with the regulatory authorities in export markets, not to mention having to compete with heavy weight generics manufacturers such as India and China.

The absence of a positive correlation between export orientation and TFP growth must also be interpreted with caution. As explained earlier, because of pricing rigidities, which have in fact been present during the entire period which saw the rise of Egypt's modern generics pharmaceutical industry, some companies have limited their exports to products -which in their judgment- reflect fair pricing and hence fair profitability levels. In the face of rare incidences of price readjustment, the majority of executives interviewed have argued that they have been limiting export activities to products on which they are incurring higher profitability levels.

Additionally, it has been argued that exporting in the case of pharmaceuticals does involve *atypical* costs, whereby pharmaceutical registration procedures in importing markets may cost as high as USD 200,000 for a single product, with no grantee that the product will eventually obtain the registration license and marketing approval. These factors may provide a possible explanation with regards the absence of a positive correlation between productivity growth and outward orientation.

The absence of evidence regarding differential efficiency performance based on privatisation status, indicates the need for re-evaluating the objectives and the overall approach to privatisation in Egypt's generics pharmaceutical sector.

6. What Has Been the Nature and Dynamics of Price Competition on the Egyptian Pharmaceutical Market?

6.1 Introduction

In this chapter, I will attempt to provide an answer to the research question concerning how far and in what ways have the regulatory framework governing Egypt's generics pharmaceutical industry allowed local companies to charge higher than average prices compared to other world markets. This chapter will also throw light on the interface between the IPRs regime which ruled up to January 2005, the pharmaceutical policy regime (including barriers facing imports of generics), and the associated impact in terms of the observed dynamics of price competition on Egypt's pharmaceutical market. The extent to which consumers (patients) have been able to capitalize fully on the cost advantage of having access to a large generics medicines manufacturing base will also be evaluated.

Three key concerns have been driving the investigation in this chapter. First, are generic-to-originator drug prices in Egypt in line with the standard ratios in major world markets. Second, has generic diffusion been bringing down average pharmaceutical price levels in Egypt? Third, within the context of an IPRs regime which excluded pharmaceutical products from patentability up to January 2005, have Egyptian consumers been fully capturing the financial benefits of having access to -relatively- cheap generics?

The importance of the analysis presented in this chapter stems from the fact that examining the nature of competition between originator and generic products, as well as between generics in Egypt has never been subject to investigation, and has been greatly neglected as well as eclipsed by the relatively larger emphasis awarded to evaluating the impact of the TRIPS Agreement on pharmaceutical supply as well as demand side actors. Of no less importance, exploring the nature of demand for generics in Egypt, the extent to which there is a need to revisit the country's national drug policy will be highlighted.

In order to address this research question, I will rely on the methodology followed by the WHO and HAI (2006) concerned with the international comparison of the prices of chronic disease medicines. The IMS Egypt database provided the main source of market data.

The examination of price competition on Egypt's pharmaceutical market has brought up some concerning results with regards generic-to-originator price levels in Egypt for the selected sample of molecules. Generic-to-originator prices in Egypt have been found to be higher than the standard ratios observed in major world markets. Of no less importance, generic diffusion has not necessarily been bringing down average prices on the Egyptian market.

On another important front, Egyptian consumers have not been fully capturing the financial benefit of having access to a large generics manufacturing base, particularly in light of a lax IPRs regime which ruled up to January 2005. Prescribing habits have resulted in a situation whereby the least priced generics were not necessarily the most prescribed. This kind of evidence throws light on the need to revisit generic policies as well as prescribing practices in Egypt.

This chapter is organized as follows. Section 6.2 presents a review of the literature to which the empirical findings of this chapter endeavour to contribute to, namely the literature covering the nature of competition in the market for pharmaceuticals. Section 6.3 presents an overview of competition on Egypt's generics market. Section 6.4 presents the empirical strategy to address the research questions posed. Section 6.5 examines the relative prices of products competing within the domain of a sample of molecules. The focus of the examination will be on the relative prices and market shares of the products examined, in conjunction with launch dates for products introduced by various companies. Section 6.6 examines the extent to which generic diffusion has been driving prices on a downward trend for late market entrants. Section 6.7 evaluates the extent to which consumers of pharmaceutical products in Egypt have been able to capitalize fully on the cost advantage of having access to a large generics medicines manufacturing base by actually consuming the least expensive products. Section 6.8 concludes with a summary of key findings.

6.2 Competition on the Market for Pharmaceutical Products

Competition on pharmaceutical markets is distinctly different from competition taking place in most markets for goods and services. Competition on the pharmaceutical market usually occurs between generics and the brand-name version of the same active ingredient instead of across products that are therapeutics substitutes. Therapeutic substitutes are products with different active ingredients, yet belong to the same therapeutic class.

In markets where pharmaceutical product patent protection in upheld, originator products enjoy a period free from generic competition, up to the date of patent expiry. Originator products usually enjoy premium prices as well as exclusivity profits during the period of patent protection. Price competition eventually becomes fierce after patent expiry, hence policies supporting price competition through the diffusion of generics after patent expiration are most important to ensuring consumer (patient) benefit. On another important front, from an industrial policy and competitiveness perspective, the empirical literature shows that increased market competition contributes to foster efficiency and to design adequate incentives to innovate (Magazzini, Pammolli and Riccaboni, 2004: 12-14)

Upon patent expiry, generic manufacturers typically enter sequentially in waves. The first to enter the market are branded generics, which accordingly, are able to capture a significant share of the entire market at a price premium. With additional generic entry, price competition intensifies. Increased competition may eventually lead to the exit of some players from the product market or some components of it (Kanavos et al, 2008: 524). The larger the number of generic equivalents which are allowed to compete within the domain of a particular molecule, the heavier is the downward pressure exerted on prices and the larger is the loss in market share originally held by the innovator product and first generic entrants.

Competition and market dynamics of this nature is nonetheless, *atypical* of markets in which pharmaceutical patent protection is absent, and in which the regulatory regime

allows only a relatively limited number of generic products to compete in the domain of a particular molecule, dosage form and strength.

Generic entry and the nature of competition on the market for pharmaceuticals

The entry of generics in a particular therapeutic class has very important implications for the nature of competition taking place between single and multiple-source drugs, as well as among multiple-source drugs. Competition of this nature is mostly translated to price revisions to the benefit of consumers (patients). Competition in the pharmaceutical markets usually takes three forms: among brand-name drugs that share therapeutic similarities, between brand-name drugs and generic substitutes, and among generic versions of the same drug (CBO, 1998).

Competition among single-source drugs

Patents do not usually grant complete monopoly power in the pharmaceutical industry. Competing research-based companies can frequently discover and patent several different drugs that use the same 'basic mechanism' to treat illness, whereby the first drug using the new mechanism to treat the illness -breakthrough drug- usually enjoys between one-to-six years on the market before a therapeutically similar patented drug (me-too drug) enters the market. Economic theory and empirical studies suggest that the presence of several therapeutically similar drugs limits the ability of manufacturers to raise prices as much as possible otherwise (CBO, 1998).

Competition between single-source drugs and generics

Regarding competition between single-source and multiple-source generic drugs, once a patent on a product expires, generic products enter the market at significant discounts to the originating brand. Discounts in fact grows larger with the increase in the number of generic competitors Examining a sample of commercially significant products coming off patent in the early to mid-1990s in the USA, indicates that after one year of generic competition, generic products were being offered at an average discount of over 50 percent relative to the originating brand, and have captured a total market share of 64 percent (Grabowski and Vernon, 2000). However, it is important to note that what happens after generic entry, is

nothing along the lines of a two-way price rivalry between branded and generic manufacturers (Scherer, 1993). There is evidence that indicates that on average, branded drug prices do increase when generic competition begins (Frank and Salkever, 1992; Grabowski and Vernon, 1992). On average, generic competition reduced the incumbent brand's prices by a modest two percent (Caves et al. 1991). Brand-name products typically loose an average of 44 percent of their market share following generic entry during the first year of competition (CBO, 1998: xii-viii).

This outcome is basically due to the fact that brand-name products try to maintain the level of profits realised prior to patent expiry by maintaining –or in some cases even increasing- their prices in order to compensate for the loss of market shares. In fact, the study by Frank and Salkever (1992) indicates that the prices of brand-name drugs do increase after generic entry, while those of existing generic drugs do tend to decrease.

Competition among generics

Economic theory suggests that product differentiation dampens price competition. When products become identical, such as with the case of generics, price competition intensifies. The more generic manufacturers enter the market, they should face increased pressure to lower prices in order to sustain their market shares (CBO, 1998: 32).

Analysis indicates that when 10 firms manufacture and distribute generic versions of a particular drug, the generic retail price of this drug falls to an average of 60-34 percent of the brand-name price. With 20 manufacturers, the generic price may well go to 20 percent of the brand-name price (CBO, 1998). Generic manufacturers are generally most profitable as first entrants into a particular market (Caves et al, 1991).

Regulatory mechanisms to accelerate generic entry

Because the costs of drugs is a concern, which is equally important in developed as well as developing countries, these costs may be potentially reduced if government regulations succeed in fostering a more powerful competition between the original manufacturers and generic substitutes (Aronsson, Bergman and Rudholm, 2001). In fact, the more competition

also takes place between generic products, the more will be the gain by consumers. In some of the world's leading pharmaceutical markets, governments have introduced mechanisms which accelerate the introduction of generic drugs. For example, in the USA, the Hatch-Waxman Act has eliminated the duplicative tests required from generic drugs to obtain regulatory and marketing approval from the FDA. Prior to 1984, manufacturers of generic drugs were actually required to prove the safety and efficacy of their products independently, being prohibited from using the unpublished test data of the innovator. Test results were considered to be trade secrets which belonged to the original manufacturer. The Hatch-Waxman Act stipulated that generic drugs were only required to demonstrate "bioequivalence" to an already approved innovator product. The test required to prove bioequivalence are much less costly and time consuming than those required proving safety and efficacy. The Act also allowed generic manufacturers to commence with their clinical tests before the patent expires, thus reducing the delay of generic entry for more than three years to less than three months for the top selling drugs. The Act also increased the proportion of brand-name drugs facing competition from generic products once their patent expire (CBO, 1998).

6.3 Competition on Egypt's Pharmaceutical Market

During the pre-Janaury-2005 phase in Egypt, pharmaceutical product patent protection has been absent, thus mechanisms driving competition cannot be fully understood against the traditional distinction made between in-patent/originator products and their chemically equivalent and bioequivalent generic competitors. In close connection, several features of Egypt's pharmaceutical regulatory regime are worth being highlighted. The absence of pharmaceutical patent protection in Egypt during the study-period, meant that competition between originator products and their generic bioequivalents became immediate once the originator product registers for marketing approval with the regulatory authorities. Registration involved the mandatory submission of a product file,[21] which -in light of the absence of data protection- is more often than not easily replicated by generic companies

[21] The file includes copies of the complete formula, quantity of active ingredients, copies of the method of analyses and a detailed illustration of the active ingredients of the finished product, data sheet including indication, contra-indications, over dose, and warning of side effects and a full scientific file for the new product including the formula, pharmacological, toxicological and clinical studies as well as stability data.

for the purpose of gaining regulatory and marketing approval. The market power of research-based companies and their ability to temporarily earn excess profit, typical of markets where IPRs standards are strong, was thus greatly circumscribed during the study period in Egypt.

In addition, the fact that the regulatory framework governing pharmaceutical registration in Egypt only allows for a maximum of four generic bioequivalent products to compete within the domain of the concerned molecule (and dosage form), has granted generic companies -particularly first movers- the power of an oligopoly to set prices in accordance to clear calculations regarding the potential threat of competition. Of no less importance with regards the brunt of competitive pressure, is the fact that regulatory barriers facing imported generics have also allowed generic manufacturers, for a very long time in Egypt, to compete *almost* exclusively amongst each other. Limited number of competing products within the domain of any specific molecule, as well as meagre generic import competition, have meant that marginal competitive pressure was levied on local generic firms to engage in price wars, which are ultimately beneficial to consumers. In addition, what also made the pre-2005 pharmaceutical market in Egypt unique is the fact that once prices were set by the regulatory authorities, they are *rarely* revised downwards, bringing out another distinct feature of price competition between various chemically and bioequivalent products.

Based on the contention that the Egyptian market for generic medicine is protected by virtue of non-tariff regulatory barriers facing generic imports, the duel effect of the ruling pharmaceutical patent regime, regulatory restraints on the number of products competing within the domain of the same molecule, and weak import competition on generic medicine prices will be examined.

6.4 Empirical Strategy, Core List of Molecules to be Examined and Sources of Data

In order to evaluate pharmaceutical pricing dynamics in Egypt, competition taking place between products falling within the domain of 21 molecules, covering a wide range of therapeutic classes will be subject to examination. The list of molecules -originally 30- has been featured in the WHO and HAI study (2006) concerned with the international

comparison of chronic disease medicines. Of the 30 molecules featured in the WHO/HAI study, only 21 were candidates for the evaluation of relative generic-to- originator prices in Egypt. The remaining molecules have been excluded, either because of limited information provided by IMS Egypt, the complete absence of generic competition or the absence of originator brands to allow for comparison.

The focus of the WHO/HAI study was on relative prices, availability and affordability of this core list of molecules. The study specified one dosage form, one strength, and one recommended pact size and up to three products to be measured:

- the originator brand
- the most sold generic equivalent (MSG)
- and the lowest price generic (LPG) equivalent for the core list of 30 molecules.

The study molecules selected as the basis for evaluating the nature of competition on Egypt's pharmaceutical market (Table 6-1) meet the criteria of being used to treat common conditions (global burden of disease), both acute and chronic that cause significant morbidity and mortality. In terms of availability, these products are also available in standard formulations and are widely used in most countries. The majority of these products are included in the WHO Model List of Essential Medicines and they represent products that are both new (in-patent in some countries) and older generations of medicines which are off-patent (WHO/HAI, 2006). As such, the selected molecules will enable the comparison and analysis of generic pricing and diffusion for mature molecules as well as for molecules which have recently gone off-patent.

Table 6-1: Core list of survey medicines

Medicine category and generic name	Strength/form	Basic patent expiry date
Antacid		
Omeprazole	20 mg	between 1998-2005
Ranitidine	150 mg	before 1998
Antiasthmatic		
Beclomethasone	50 mcg dose	before 1998
Salbutamol	0.1 mg/ dose	before 1998
Antibacterial		
Amoxicillin	250 mg	before 1998
Ceftriaxone	1 gm	between 1998-2005
Ciprofloxacin	500 mg Tablet	after 2005
Co-Trimoxazole	8+ /40 mg/ml	before 1998
Antidepressant		
Amitriptyline	25 mg - 30	before 1998
Fluoxetine	20 mg - 20	between 1998-2005
Antidiabetic		
Glibenclamide	5 mg - 20 Tab	before 1998
Metformin	500 mg - 10	before 1998
Antiepileptic		
Carbamazepine	200 mg - 10	before 1998
Phenytoin	100 mg - 50	before 1998
Antifungal		
Fluconazole	200 mg	between 1998-2005
Antihypertensive		
Atenolol	50 mg - 10	before 1998
Captopril	25 mg - 20	before 1998
Hydrochlorothiazide	25 mg - 30	before 1998
Losartan	50 mg - 7 Tab	after 2005
Nifedipine Retard	20 mg - 30	before 1998
Anti-Inflammatory		
Diclofenac Sodium	25 mg - 30	before 1998
Antimalarial		
Artesunate	n.a.	before 1998
Pyrimethamine	25 mg - 6 Tab	before 1998
Antipsychotic		
Fluphenazine Decanoate	25 mg 1 ml -	before 1998
Antiviral		
Acyclovir	200 mg - 20	before 1998
Indinavir	n.a.	after 2005
Nevirapine	n.a.	after 2005
Zidovudine	100 mg - 100	between 1998-2005
Anxiolytic		
Diazepam	5 mg - 20 Tab	before 1998
Serum Lipid Reducing		
Lovastatin	20 mg - 10	between 1998-2005

Source: WHO/HAI, 2006

Data sources

Market data from the IMS database for Egypt pertaining to the molecules under examination has been relied on for the assessment undertaken in this chapter. IMS Egypt provides historical data covering details concerning dispensed medicines in the retail pharmaceutical market (pharmacies) for a period up to six years. The analysis is, therefore, limited to the period between 2003 and 2008, for which data is available. The prices of products subject to examination have been cross-checked with the prices provided by the Drug Planning and Policy Center of the Ministry of Health in Egypt. Because of differences in pack size (for the same strength), comparisons are made on the basis of unit prices, whereby the price per pack was divided by the number of fillings.

IMS data provides details concerning product brand names, manufacturers' name, launch dates, sales volume and value as well as price data for the products competing in the domain of the 21 candidate study molecules. IMS data has been be used to identify the prices, launch dates, and market shares of originator brands, the least priced generic (LPG) and the most sold generic (MSG) for the study molecules. The information was provided with full reference to whether the product belongs to the public business sector, the multinational sector (subsidiaries of research-based companies with manufacturing facilities in Egypt) or the local generics sector. In addition, the information is also classified according to whether the product is imported or manufactured locally (including agreements for toll-manufacturing).

6.5 Relative Prices of Originator Products and Their Generic Bioequivalent Products in Egypt

Because it was not feasible to examine the prices of all generic products relative to originator products on the Egyptian market, the evaluation was confined to the list of 21 molecules operating in the domain of 14 therapeutic classes. The 21 study-molecules account for 4.4 percent of Egypt’s pharmaceutical market, and involved competition between some 196 products. Table 6-2 presents the market shares of the sample-molecules, as well the share of generic products within the domain of each subsequent molecule. As

evident from Table 6-2, in 17 of the study molecules, generics dominate as the key players by virtue of accounting for the largest market shares. In 4 molecules, innovator brands dominate subsequent market shares.

Table 6-2: Market share of sample molecules

		Units ('000)		LE Sales ('000)	
		2003	2008	2003	2008
	Egyptian market	849,159	1,323,496	5,474,280	12,565,859
	Share of sample-21 molecules (%)	3.32	3.68	5.03	4.36
	Antacid				
1	OMEPRAZOLE				
	Market for Omeprazol (value)	1,181.1	2,740.1	31,651.5	69,245.1
	Share of retail market (%)	0.1	0.2	0.6	0.6
	Generic Share of Omeprazole market (%)	96.9	98.9	94.3	97.9
2	RANITIDINE				
	Market for Ranitidine (value)	5,830.1	14,073.6	65,156.4	137,947.3
	Share of retail market (%)	0.7	1.1	1.2	1.1
	Generic Share (%)	61.2	67.6	39.5	44.5
	Antiasthmatic				
3	BECLOMETASONE				
	Market for BECLOMETHAZONE (value)	931.4	1,364.2	11,178.1	22,246.5
	Share of retail market (%)	0.1	0.1	0.2	0.2
	Generic Share (%)	100.0	100.0	100.0	100.0
	Antibacterial				
4	AMOXICILLIN				
	Market for AMOXICILLIN (value)	1,310.3	1,088.3	4,945.9	6,883.2
	Share of retail market (%)	0.2	0.1	0.1	0.1
	Generic Share (%)	81.7	86.5	83.1	90.4
5	CEFTRIAXONE				
	Market for CEFTRIAXONE (value)	240.8	1,609.3	8,714.8	45,435.3
	Share of retail market (%)	0.0	0.1	0.2	0.8
	Generic Share (%)	42.2	64.4	39.7	56.8
6	CIPROFLOXACIN (%)				
	Market for CIPROFLOXACIN (value)	1,160.8	3,173.8	33,060.7	84,831.6
	Share of retail market (%)	0.1	0.2	0.6	1.5
	Generic Share (%)	59.4	59.8	63.9	69.9
	Antidepressant				
7	AMITRIPTYLINE				
	Market for AMITRIPTYLINE (value)	473.1	448.2	1,784.4	1,679.3
	Share of retail market (%)	0.06	0.03	0.03	0.03
	Generic Share (%)	100.0	100	100	100
8	FLUOXETINE				
	Market for FLUOXETINE (value)	480.6	643.3	7,926.8	11,500.2
	Share of retail market (%)	0.1	0.0	0.1	0.0
	Generic Share (%)	94.1	97.7	94.1	97.7
	Antidiabetic				
9	GLIBENCLAMIDE				
	Market for GLIBENCLAMIDE (value)	3,738.6	3,213.2	13,956.9	14,945.1
	Share of retail market (%)	0.4	0.2	0.3	0.12
	Generic Share (%)	-	3.4	-	4.4
10	METFORMIN				
	Market for METFORMIN (value)	2,036.5	2,649.6	5,113.5	11,469.6
	Share of retail market (%)	0.2	0.2	0.1	0.09
	Generic Share (%)	91.4	74.4	84.7	40.3

Cont. Table 6.2: Market share of sample molecules

		Units (thousands)		LE Sales ('000)	
		2003	2008	2003	2008
	Antidiabetic				
11	CARBAMAZEPINE				
	Market for carbamazepine (value)	2,269.3	2,216.2	19,934.2	33,630.5
	Share of retail market (%)	0.3	0.2	0.4	0.3
	Generic Share (%)	100.0	95.7	100.0	98.9
12	PHENYTOIN				
	Market for PHENYTOIN (value)	180.5	256.7	1,816.2	3,128.7
	Share of retail market (%)	0.02	0.02	0.03	0.06
	Generic Share (%)	99.8	93.0	99.9	90.9
	Antifungal				
13	FLUCONAZOLE				
	Market for FLUCONAZOLE (value)	968.6	2,289.9	14,311.8	31,454.7
	Share of retail market (%)	0.1	0.2	0.3	0.6
	Generic Share (%)	80.1	84.0	67.0	68.5
	Antihypertensive				
14	ATENOLOL				
	Market for ATENOLOL (value)	1,968.8	3,036.8	11,857.4	18,597.7
	Share of retail market (%)	0.2	0.2	0.2	0.2
	Generic Share (%)	32.2	89.4	22.6	82.1
15	CAPTOPRIL				
	Market for CAPTOPRIL (value)	1,825.9	1,851.8	15,832.2	24,930.0
	Share of retail market (%)	0.2	0.1	0.3	0.5
	Generic Share (%)	37.8	99.2	43.0	99.6
16	LOSARTAN				
	Market for LOSARTAN (value)	283.0	598.8	10,694.5	19,367.0
	Share of retail market (%)	0.03	0.0	0.2	0.35
	Generic Share (%)	52.3	67.4	43.1	53.1
17	NIFEDIPINE				
	Market for NIFEDIPINE (value)	839.1	5,740.3	4,609.9	8,006.1
	Share of retail market (%)	0.1	0.4	0.1	0.1
	Generic Share (%)	90.9	24.3	87.4	100.0
	Anti-inflammatory				
18	DICLOFENAC				
	Market for DICLOFENAC (value)	1,772.6	1,565.9	8,986.3	11,116.9
	Share of retail market (%)	0.2	0.1	0.2	0.2
	Generic Share (%)	51.4	56.7	45.9	38.1
	Antiviral				
19	Acyclovir				
	Market for Acyclovir (value)	75.6	106.9	958.9	1,335.4
	Share of retail market (%)	0.01	0.01	0.02	0.02
	Generic Share (%)	16.5	15.0	27.3	25.1
	Anxiolytic				
20	DIAZEPAM				
	Market for DIAZEPAM (value)	643.0	956.3	484.6	1,108.9
	Share of retail market (%)	0.1	0.1	0.0	0.0
	Generic Share (%)	100.0	100.0	100.0	100.0
	Serum lipid reducing				
21	LOVASTATIN				
	Market for LOVASTATIN (value)	3.4	4.9	57.9	83.9
	Share of retail market (%)	0.00	0.00	0.00	0.00
	Generic Share (%)	100	100	100	100

Source: Based on IMS, 2009

For each of the study molecules, the prices of all generic products competing in the domain of the concerned molecule (same dosage form and strength) were observed, starting from the first to the last market entrant to obtain regulatory approval. Generic prices are compared to the price of the originator product. For molecules which are relatively mature, the price of products manufactured by research-based pharmaceutical companies, whether imported or manufactured locally, was taken as the benchmark for comparison.

A key finding prsented was that in only 4 out of 18 molecules (3 molecules have been excluded because there was no originator brand to compare with), the price of the examined list of generic equivalents went below the 50 percent threshold of the price of the originator brand (Presented in detail in Annex 11). In 9 molecules, atypical generic-to-innovator prices were observed. What was even more important to note, is the finding that generic diffusion has not been bringing down average prices on the Egyptian market to any levels of significance. With only one exception, for products competing within the domain of the 21 molecules, the prices of subsequent market entrants were either clustered around the first entrant, or went above it (Details presented in Table 6-4).

The following sections detail the results concerning relative prices in the domain of the 9 molecules in which atypical generic-to-innovator prices were observed. For products competing within the domain of each molecule, a table indicating the prices charged by each new market entrant is presented to document the phenomenon of atypical generic-to-originator prices.

Antibacterial

The first case documenting higher than standard generic-to-originator prices in the sample-molecules fell in the domain of Amoxicillin. Because Amoxicillin is a relatively mature molecule -its basic patent expired before 1998- the expectation was that generic competition was likely to be prolific. In the domain of Amoxicillin, a total of 5 generic companies compete over market shares for the dosage from and strength examined against Bristol-Myers Squibb's (BMS) originator brand 'Hiconcil', which was first marketed in Egypt in 1990. Amoxicillin generic-to-originator prices range between 60-167%

1. **Amoxicillin caps 250 mg**

Sector	Company	Product	Launch year	Public price	Price per unit	Generic-to-originator Prices perce
Originator Multinational	BMS	Hiconcil	1990	4.5	0.38	
Holdi Pharma	CID	Amoxycid	1980	4.3	0.36	96
Private	AMOUN.	Ibiamox	1981	3.7	0.31	82
Private	EIPICO	Flumox	1985	7.5	0.63	167
Private	SEDICO	Flucamox	1994	6.3	0.53	140
Private	SEDICO	Biomox	1997	5.3	0.44	118
Holdi Pharma	ADCO	Amoxycillin	n.a.	2.7	0.23	60

The antibacterial market provided another example of atypical generic-to-originator prices. Ciprofloxacin is a relatively new molecule, with the patent expiry date falling after 2005. The prices of the generic versions of 'Ciprofloxacin' which range between 88-140 percent stand in sharp contrast to standard global ratios as detailed in Chapter Three.

2. **Ciprofloxacin tabs 500 mg**

Sector	Company	Product	Launch year	Public price	Price per unit	Generic-to-originator Prices
Originator Multinational	SANDOZ	Serviflox	1997	28.0	0.36	
Private	EIPICO	Ciprocin	1996	32.0	0.31	88
Holdipharma	CID RANBAXY	Rancif	1997	22.5	0.44	124
Holdipharma	MISR	Mifoxin	1997	29.7	0.34	94
Private	PHARCO	Ciprofar	2002	20.0	0.50	140
Private	EURO.EGY.PH.	Ciprofloxacin	2006	30.0	0.33	93

Antidiabetic

In the antidiabetic class, in the domain of the 'Glibenclamide' molecule, Roche's originator product 'Euglucon' had one generic competitor, namely Pharco's product 'Diaben'. Diaben was marketed in Egypt starting 1988, some 8 years following the entry of 'Euglucon'. The absolute absence of generic competition allowed Pharco to price its product at a staggering 107 percent of the price of the originator brand.

3. **Glibenclamide tabs** 5 MG

Sector	Company	Product	Launch year	Public price	Price per unit	Generic-to-originator Prices %
Originator Multinational	GLAXO EG.	Euglucon	1980	2.8	0.09	
Private	PHARCO	Diaben	1988	2.0	0.10	107.1

Metformin is the second molecule examined in the antidiabetic class. Despite the fact that a total of 5 generics companies and 9 products (in various dosage forms) compete cover market shares, standard generic-to-innovator prices have remained absent. Generic-to-originator prices range between 100-300 percent.

4. **Metformin tabs 500 MG**

Sector	Company	Product	Launch year	Public price	Price per unit	Generic-to-originator Prices %
Originator Multinational	Novartis egypt	Glucoformin	2002	2.0	0.10	
Originator Multinational	Novartis egypt	Glucoformin	2002	8.0	0.10	
Holdipharma	Nasr	Metformin	0000	20.0	0.10	100
Holdipharma	Cid	Cidophage	1996	1.3	0.13	130
Holdipharma	Cid	Cidophage	1996	2.5	0.13	125
Holdipharma	Cid	Cidophage	1997	62.5	0.13	125
Holdipharma	Nasr	Metformin	1999	3.0	0.10	100
Private	Amoun	Amophage	2000	1.5	0.15	150
Private	Amoun	Amophage	2000	4.5	0.15	150
Private	Pharco	Diaformin	2000	2.0	0.10	100
Private	Pharaonia.	Diaphage	2001	2.0	0.10	100
Private	Minapharm merck	Glucophage	2006	15.0	0.30	300

Antiepileptic

In the antiepileptic market, the Phenytoin molecule provides further evidence of the above standard generics prices. The prices of generic products which entered the market between 1998 and 2006 ranged between 100-145 percent of the price of the originator product, which was introduced in 1995.

5. **Phenytoin caps 100 mg**

Sector	Company	Product	Launch year	Public price	Price per unit	Generic-to-originator Prices %
Originator Multinational	NILE PFIZER	Epanutin	1995	10.0	0.10	
Originator Multinational	NILE PFIZER	Epanutin	2000	12.0	0.24	
Holdipharma	NASR	Phenytoin	1998	5.8	0.15	145
Holdipharma	NILE	Phenytin	2004	12.0	0.24	100
Holdipharma	ARAB GELAT.	Ipanten	2005	16.0	0.32	133
Holdipharma	MEMPHIS	Phenytoin	2006	14.0	0.28	117

Antihypertensive

In the antihypertensive market, a total of five companies compete in the domain of the Captopril molecule, with generic-to-innovator prices ranging between 60-70 percent.

6. **Captopril tabs 25 MG**

Sector	Company	Product	Launch year	Public price	Price per unit	Generic-to-originator Prices %
Originator Multinational	BMS EGYPT	Capoten	1983	10.0	0.50	
Originator Multinational	BMS EGYPT	Capoten	2003	20.0	0.50	
Originator Multinational	GSK EG	Capoten	2008	10.0	0.50	
Originator Multinational	GSK	Capoten	2008	20.0	0.50	
Holdipharma	KAHIRA	Lontensin	1995	7.0	0.35	70
Private	EIPICO	Capotril	1996	6.4	0.32	64
Private	AMOUN	Hypopress	1999	3.0	0.30	60

Nifedipine is another molecule examined in the antihypertensive market, in which generic-to-innovator prices ranged between 96-150 percent.

7. **Nifedipine tabs 20 MG**

Sector	Company	Product	Launch year	Public price	Price per unit	Generic-to-originator Prices %
Originator Multinational	ALEXANDRIA BAYER	Adalat	1995	10.5	0.35	
Private sector	EIPICO	Epilat	1989	10.5	0.53	150
Private sector	MINAPHARM B.O.I	Dilcor	1992	6.7	0.33	96
Private sector	SIGMA TIBA	Tenolat	2003	10.0	0.50	143
Private sector	SIGMA TIBA	Tenolat	2004	15.0	0.50	143

Anti-inflammatory

In the anti-inflammatory market, generic-to-innovator prices in the domain of the Diclofenac molecule range between 53-106 percent, despite active competition between 9 generic companies which entered the Egyptian market between 1991 and 2008.

8. **Diclofenac tabs 25 MG 30**

Sector	Company	Product	Launch year	Public price	Price per unit	Generic-to-originator Prices %
Originator Multinational	NPE NOVARTIS	Voltaren c.h.	1989	11.3	0.38	
Originator Multinational	NOVARTIS PH.	Cataflam	1991	5.0	0.50	
Originator Multinational	NOVARTIS PH.	Cataflam	2005	10.0	0.50	
Private sector	PHARCO	Declophen	1991	4.5	0.23	60
Private sector	SEDICO	Rheumarene	1994	4.8	0.24	64
Holdipharma	NASR	Diclofenac	1995	6.0	0.20	53
Private	MUP MEPHA	Olfen	1995	10.5	0.35	93
Multinational	GSK EG	Rheumafen	1996	6.9	0.35	92
Private	T3A	Antiflam	1998	3.4	0.34	90
Private	MINAPHARM	Potafen	1999	3.3	0.33	88
Private	MUP MEPHA	Oflam	2000	3.5	0.35	93
Multinational	GSK EG	Rapiflam	2004	4.0	0.40	106
Private	MINAPHARM	Potafen	2005	6.5	0.33	86
Private	DELTA	Dolphin-k	2008	6.0	0.30	80
Private	EIPICO	Epifenac	2008	4.0	0.20	53

Antiviral

In the Antiviral market, generic-to-innovator price in the domain of Acyclovir stands at 76 percent, with only one generic product competing against the originator brands Novirus and Zovirax of GSK.

9. **Acyclovir**

Sector	Company	Product	Launch year	Public price	Price per unit	Generic-to-originator Prices %
Originator Multinational	GSK EG	Novirus	1994	11	1.38	
Private sector	SEDICO	Cycloviral	1997	21	1.05	76

One important observation regarding the above expose of generic-to-innovator prices is that, generic import competition is virtually absent. This observation raises concern regarding the association of higher than average generic-to-innovator prices with the absence of import competition.

6.6 Has Generic Diffusion Contributed to Bringing down Average Prices on Egypt's market for pharmaceuticals?

One of the benefits of generic diffusion is that with each new market entrant, prices are usually brought down further, mostly to the benefit of consumers. To evaluate the extent to which the highly genericised pharmaceutical market in Egypt supports this healthy phenomenon, prices charged by each new generic market entrant in the domain of the sample molecules were evaluated against the prices of competitors, which entered the market of the concerned molecules at an earlier stage.

The following sections detail price dynamics during the period which elapses between the entry of the first and last generic products in the domain of 19 of the sample molecules. Two out of the 21 study molecules have been excluded from the analysis. Amitriptyline in the antidepressant market was excluded as there has been only one product manufactured by the public sector company Kahira present. Acyclovir in the domain of antivirals was also excluded as the only two products on the market were GSK's Novirus and Zovirax.

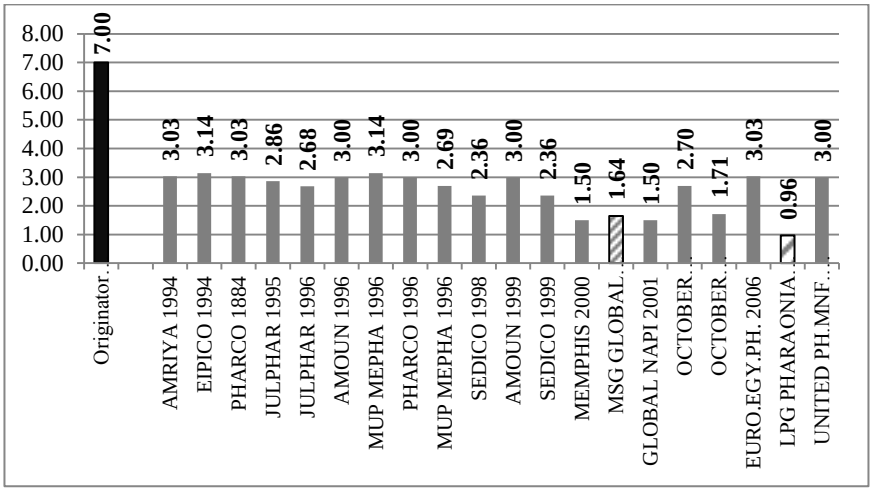
The trend is also presented in relation to the price of the originator brand. On the graphs pertaining to each product, indications will be made with reference to the originator brand, the most sold generic (MSG) and the least priced generic (LPG). The same company may appear twice on the graphs, since the same product can be available in various doses. Companies appearing on the graphs are to begin with the first to enter the market and end with the last market entrant. In each graph, the first column represents the manufacturer of the originator brand/ first market entrant.

Results have indicated that generic diffusion has not been bringing down average prices on the Egyptian market to any levels of significance. With only one exception, for products competing within the domain of the 19 molecules, the prices of subsequent market were either clustered around the first entrant, or went above it.

Antacid: Omeprazole and Ranitidine

In the antacid therapeutic class, the first molecule examined was **'Ompeprazole'**. Ompeprazole has been approved as a new molecular entity (NME) in the USA by the FDA for marketing in September, 1989, and the basic patent expiry date fell between 1998 and 2005 (Orange Book, 2011; WHO/HAI, 2006). The originator brand 'Losec' was introduced to the Egyptian market as an imported product by AstraZeneca in 1993, selling at LE 10 per unit. One year following the introduction of Losec on the Egyptian market, the first two generic competitors were launched in 1994, under the brand names 'Gastrazole' by Amriya Pharmaceuticals, selling at LE 3.03 per unit, and 'Epiraz' by EIPICO selling at LE 3.14 per unit. By 2007, a total of 13 generic companies in the domain of Ompeprazole were competing, with the unit price of the last entrant being LE 3. Despite the fact that the market for the 'Ompeprazole' molecule embraced a large number of generic competitors, the 13-year period which elapsed between the launch of the first generic competitor and the last market entrant did not see a large drop in the mean price per unit.

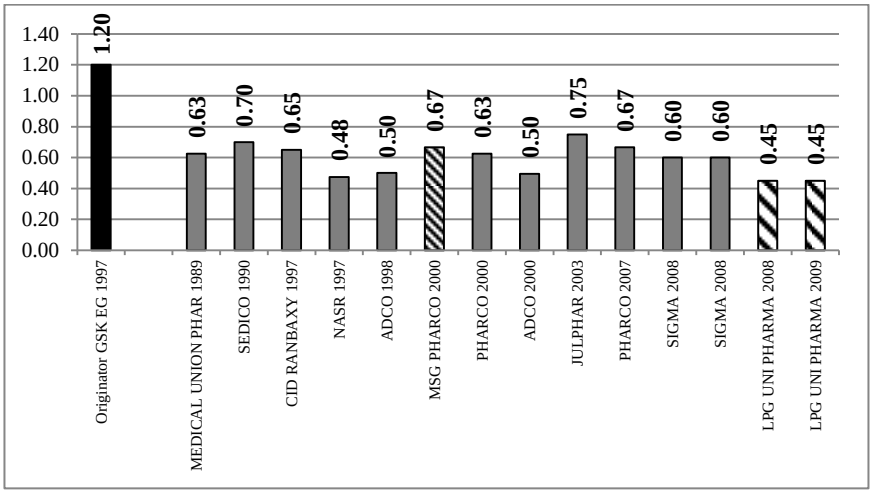
Figure 6-1: Relative prices in the Ompeprazole molecule (LE per unit)



The second molecule examined in the antiacid market was **'Ranitidine'**. Ranitidine was approved by the USA FDA as a new molecular entity in June, 1983, with its basic patent expiry date falling before 1998. In Egypt, the generic version of ranitidine was introduced to the market in 1989 under the brand name 'Ranitidine' by Medical Union Pharmaceuticals, selling at LE 0.63 per unit. Five years later, GSK's originator product

'Zantac' entered the market, selling at LE 1 per unit. Zantac was manufactured by GSK's subsidiary in Egypt under license from the mother company. Between 1989 and 2009, a total of 10 generic companies entered the market. Examining the price per unit of products entering this market segment sequentially, indicates that price levels have not experienced significant reductions over this 20-year period.

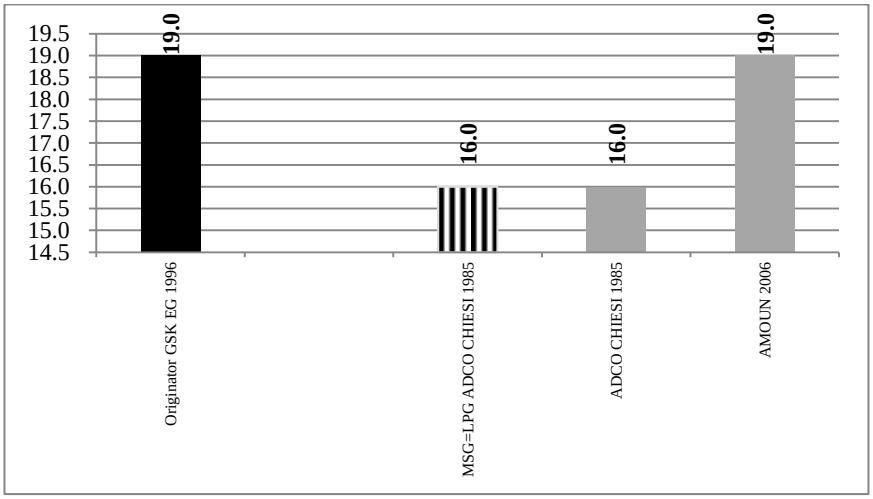
Figure 6-2: Relative prices in the Ranitidine molecule (LE per unit)



Antiasthmatics: Beclometasone

In the antiasthmatic therapeutic class, **'Beclometasone'** was introduced to the Egyptian market in 1985, under the brand name 'Clenil' by Chiesi under a special toll manufacturing agreement with the public business sector company ADCO, selling at LE 16 per inhaler. In 1996, GSK introduced its brand 'Becon Spray', selling at LE 19 per inhaler. The market for the Beclometasone molecule (50 mcg dose) is highly concentrated in Egypt, whereby only two generic products are present on the market. In 2006, Amoun introduced the second generic version of Beclometasone under the brand name 'Beclo' selling at LE 19 per unit, which is the same price as the originator manufactured by the subsidiary of GSK in Egypt.

Figure 6-3: Relative prices in the Beclometasone molecule (LE per unit)

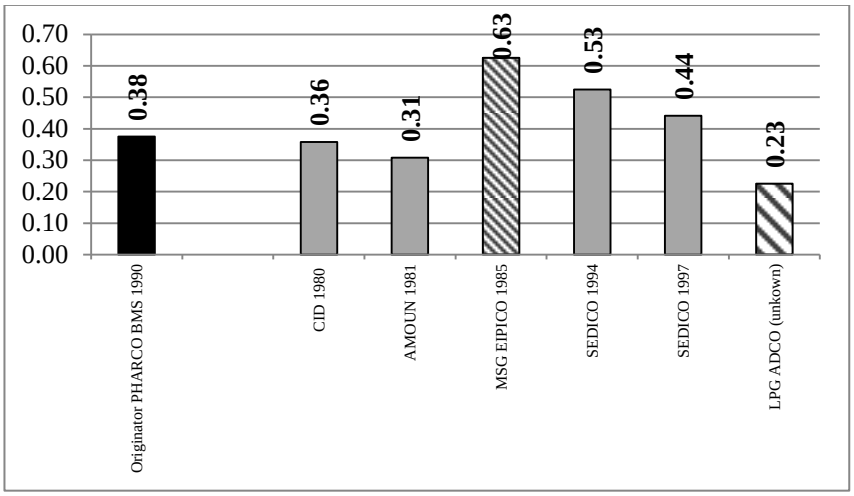


Antibacterials: Amoxicillin, Ceftriaxone and Ciprofloxacin

Four molecules falling under the therapeutic class of antibacterials have been examined. **'Amoxicillin'** was first introduced to the Egyptian market by BMS in 1977 through its brand name 'Hiconcil'. Given the considerable maturity of this therapeutic class, a relatively large number of manufacturers compete in the domain of the Amoxicillin molecule under an equally large number of strengths and dosage forms. The focus of the analysis has been on the 250 MG capsules specified in the WHO/HAI (2006) study. The first 250 MG capsule form of Amoxicillin was introduced by the public business sector company CID in 1980, selling at LE 0.36 per unit. Between 1980 and 1997[22], a total of 5 generic companies were competing in the domain of the dosage form and strength subject to examination, in addition to BMS's brand 'Hiconcil' which was launched in 1994, selling at LE 0.38 per unit. The last market entrant in 1997 was SEDICO's brand 'Biomox' which sold at LE 0.44 per unit. The prices of the majority of new entrants into the domain of Amoxicillin 250 MG capsules domain have been higher than that of the initial entrant. In fact, the most sold generic version of Amoxicillin 250 MG capsules is EIPICO's brand name 'Flumox', which sells at double the price of both the first generic entrant as well as that of BMS's brand-product 'Hiconcil'.

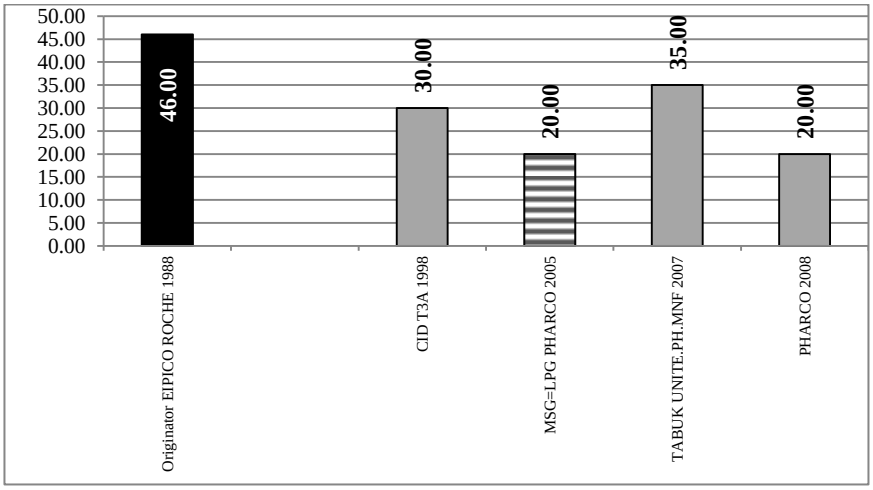
[22]ADCO's product Amoxycillin was launched on a date not specified by IMS data.

Figure 6-4: Relative prices in the Amoxicillin molecule (LE per unit)



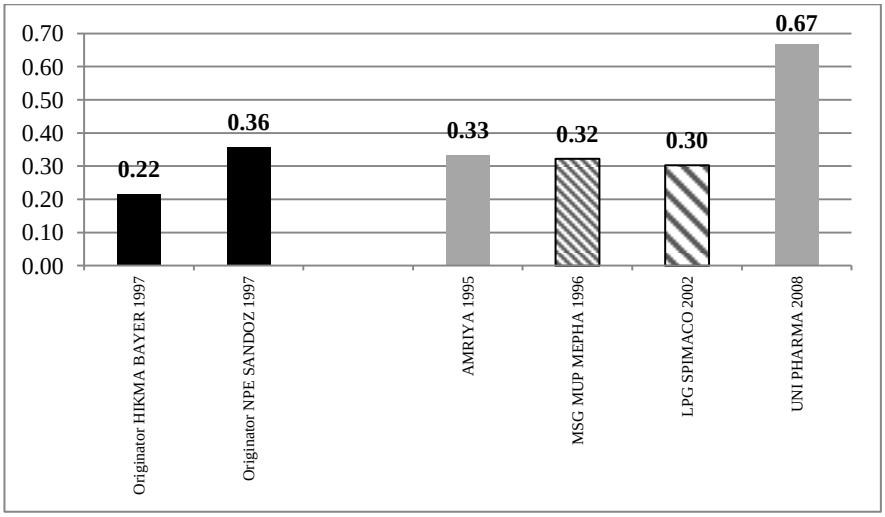
A total of five products compete in the domain of the **'Ceftriaxone'** molecule (V.IM Dry 1G1 unit). The first market entrant was Roche in 1988 through a special toll manufacturing agreement with the local generic company EIPICO. Roche's brand 'Rocephin' sold at LE 46 per unit. Within the domain of the examined dosage form and strength, four new products entered the market during the ten-year period between 1998 and 2008. The first generic company to enter the 'Ceftriaxone' 1G market was T3A under a special toll manufacturing agreement with the public business sector company CID, selling at LE 30 per unit. This price stood at 65 percent of the price of the Roche's originator product. The last entrant to the market in 2008, actually brought down prices to 43 percent of the price of the originator product, with Pharco's brand 'Cefaxone' selling at LE 20 per unit.

Figure 6-5: Relative prices in the Ceftriaxone molecule (LE per unit)



The last molecule to be examined in the domain of antibacterials is **'Ciprofloxacin'**, which is a relatively mature molecule, as it was first patented in 1983 by Bayer. In the domain of 'Ciprofloxacin', a total of 4 generic companies compete in the 500 MG tablets market. The first market entrant was the local generic company Amriya through its brand 'Ciprocin' in 1996, selling at LE 0.33 per unit. In 1997, Bayer launched its product 'Ciprobay' selling at a much lower price of LE 0.22 per unit. Further generic entry to the domain of the Ciprofloxacin' molecule (500 MG tablets) actually increased generic unit prices beyond that of the initial entrant.

Figure 6-6: Relative prices in the Ciprofloxacin molecule (LE per unit)

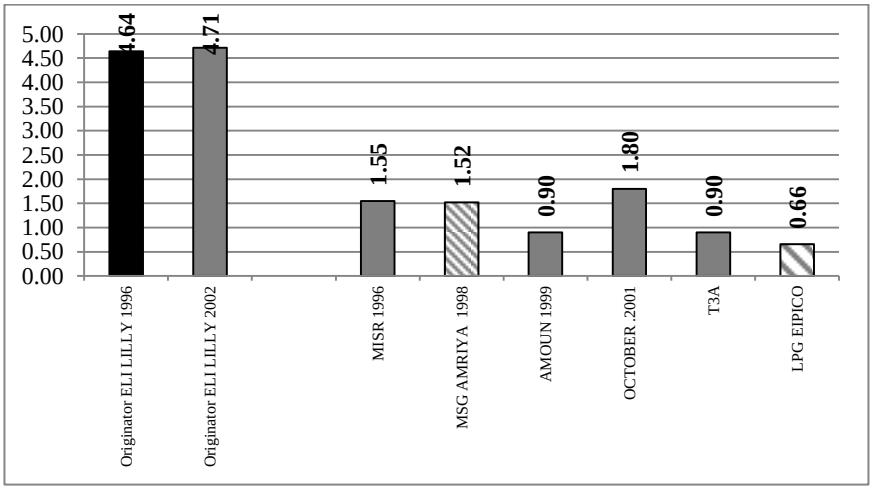


Antidepressants: Amitriptyline and Fluoxetine

In the antidepressants therapeutic class, competition in the domain of two molecule was examined, namely **'Amitriptyline'** and**'Fluoxetine'**. The market for 'Amitriptyline' is highly concentrated in Egypt, with the public business sector pharmaceutical company Kahira having the only product on the market, namely 'Tryptizol' selling at LE 5 per 10 MG tablet and LE 3.5 per 25 MG tablet.

The second molecule examined in the antidepressants class was '**Fluoxetine'**, which was approved by the US FDA as a NME in December 1987. Fluoxetine was introduced to the Egyptian market in 1996 through the originator product 'Prozac', which was imported by Eli Lilly and sold at LE 4.68 per unit of 20 MG capsule. During the same year, the public business sector company Misr introduced the competing product 'Fluxotine' which sold at LE 1.55 per unit. By the date the last generic product in the domain of the 'Fluoxetine' molecule entered the market, the unit price was more than halved to reach LE 0.66.

Figure 6-7: Relative prices in the Fluoxetine molecule (LE per unit)

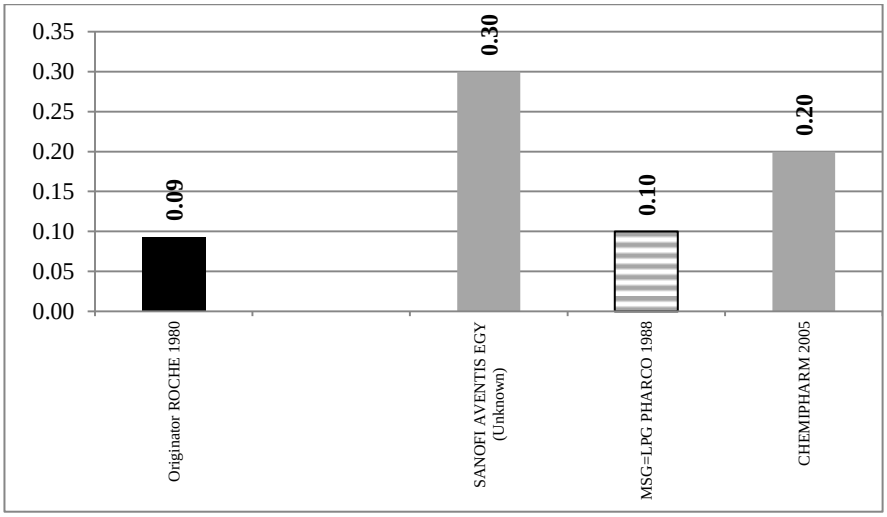


Antidiabetics: Glibenclamide and Metformin

Pricing in the domain of two molecules in the antidiabetics therapeutic class has been examined. In the domain of the **'Glibenclamide'** molecule, the first product to be launched in Egypt was Roche's brand 'Euglucon' in 1980, selling at LE 0.09 per unit of 5 MG tablets.

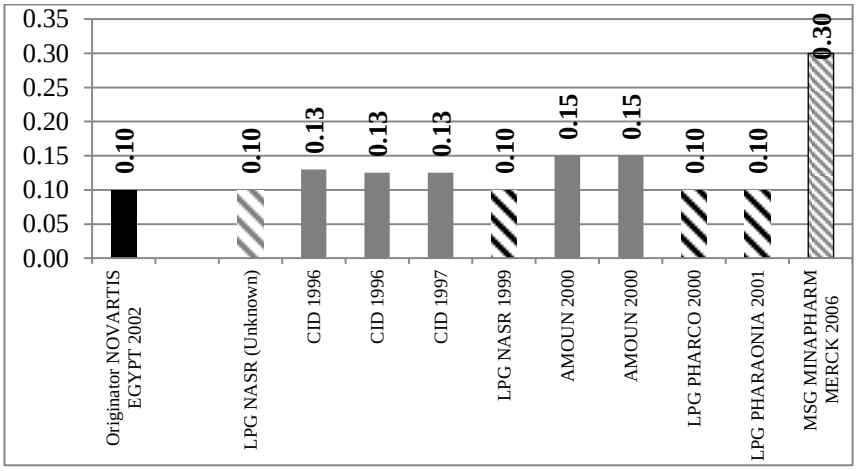
In 1988, the first and only generic competitor appeared on the market, when Pharco's 'Diaben' began to be marketed, selling at LE 0.10 per unit. The price of the generic version of Glibenclamide stands at 107 percent of the price of the originator product.

Figure 6-8: Relative prices in the Glibenclamide molecule (LE per unit)



The second molecule examined is **'Metformin'**, which was first marketed in France in 1979, and received approval by the USA FDA for Type 2 diabetes in 1994. In 2002, Novartis Egypt launched its brand product 'Glucoformin' selling at LE 0.10 per unit of 500 Mg tablets. Generic diffusion in the domain of the 'Metformin' molecule was relatively extensive in Egypt, with a total of 5 companies and 9 products (because of different dosage forms and strengths) on the market. The first product to enter the Egyptian market in 1996 was CID's brand 'Cidophage', which sold at LE 0.13 per unit. Surprisingly, and contrary to expectation, further generic entry was either priced exactly the same as the first entrant or at higher unit prices.

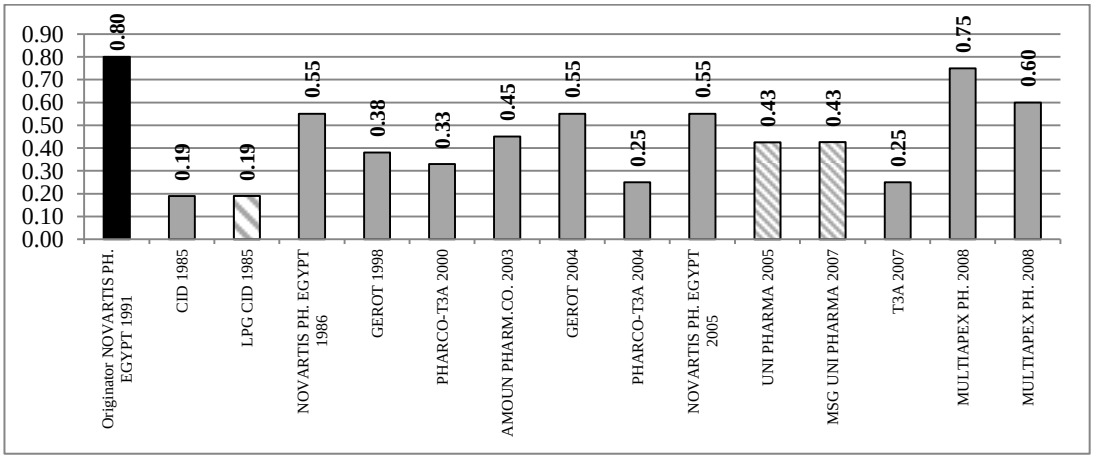
Figure 6-9: Relative prices in the Metformin molecule (LE per unit)



Antiepileptic: Carbamazepine and Phenytoin

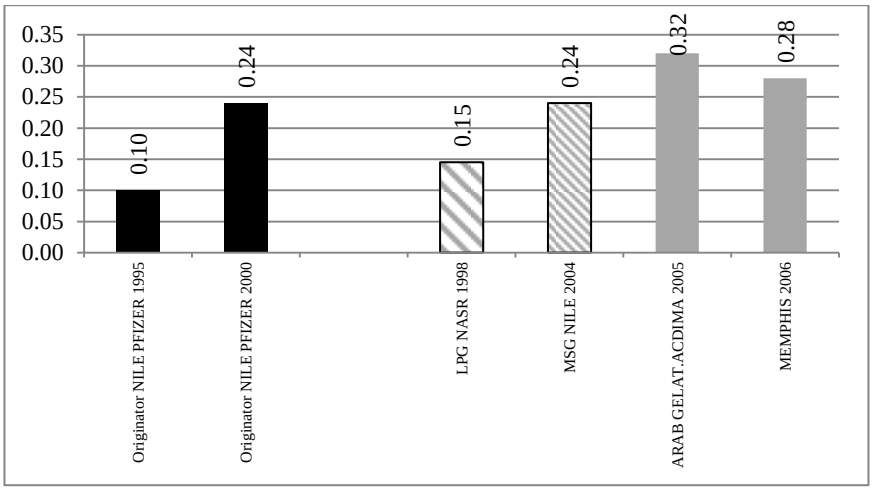
In the antiepileptic class, two molecules **'Carbamazepine'** and **'Phenytoin'** were examined. Carbamazepine is a relatively mature molecule, as it was first marketed as a drug to treat trigeminal neuralgia in 1962, and has been used as an anticonvulsant in the UK since 1965. Carbamazepine has been approved in the USA since 1974. Carbamazepine was launched on the Egyptian market in 1985 under the brand name 'Tegral' by the public business sector company CID, selling at LE 0.19 per unit. In 1991, Novartis lunched its brand 'Tegretol' through its local subsidiary, selling at LE 0.8 per unit. A total of 14 generic products compete in the Carbamazepine market, whereby generic diffusion did not lead to any lowering of significance in price levels.

Figure 6-10: Relative prices in the Carbamazepine molecule (LE per unit)



The second molecule examined, **Phenytoin,** is also a relatively mature one, having been first synthesized by German chemist Heinrich Biltz in 1908 (http://en.wikipedia.org). Phenytoin was first launched on the Egyptian market in 1995 by Pfizer, selling at LE 0.24 per unit. The first generic competitor appeared on the market in 1998, through the entry of the brand of Nasr Company Pheny at LE 0.15 per unit. Four generic products compete in the Phenytoin market, with the each subsequent entrant raising the price much further beyond the initial entrant.

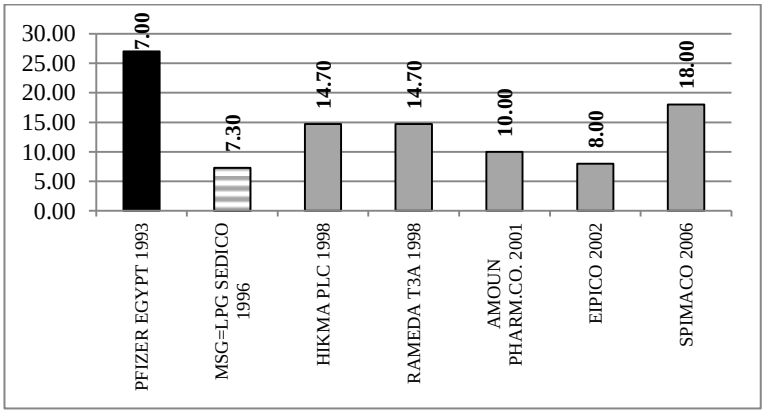
Figure 6-11: Relative prices in the Phenytoin molecule (LE per unit)



Antifungal: Fluconazole

In the antifungal therapeutic class, one molecule was examined, namely '**Fluconazole**'. Pfizer received approval from the US FDA to market Fluconazole in 1990 under the brand name 'Diflucan', with the patent expiry date falling between 1998 and 2005. Diflucan was first introduced to the Egyptian market by Pfizer Egypt in 1993, selling at LE 27 per unit. In 1996, the first generic competitor appeared on the market, following the entry of SEDICO's brand Flucoral, which sold at LE 7.3 per unit. With only one exception, each new generic entrant to the market increased the level of unit prices beyond that of the initial entrant.

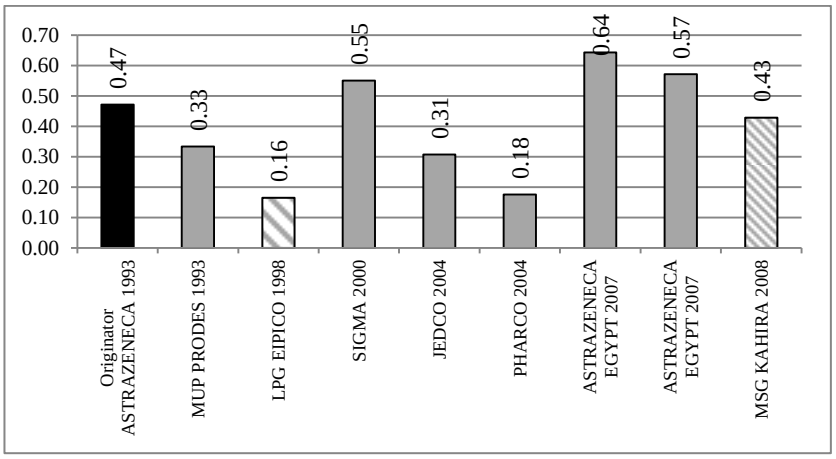
Figure 6-12: Relative prices in the Fluconazole molecule (LE per unit)



Antihypertensive: Atenolol, Captropril, Losartan and Nifedipine

In the Antihypertensive class, four molecules were examined. The first is the domain of the **'Atenolol'** molecule, for which AstraZeneca received regulatory approval from the US FDA to market its brand name 'Tenormin' in 1981. Tenormin was first brought to Egypt by AstraZeneka through a toll manufacturing agreement with the public business sector company Kahira in 1993, selling at LE 0.47 per unit. The first generic competitor appeared in 1993, when Prodes manufactured its brand 'Blokium' through a toll manufacturing agreement with MUP, selling at LE 0.33 per unit. The first Egyptian, generic product was launched in 1998, when EIPICO marketed its product 'Ateno', selling at LE 0.16 per unit. All generic entries beyond 1998, were launched at much higher unit prices compared to the first entrant.

Figure 6-13: Relative prices in the Atenolol molecule (LE per unit)



For the **'Captropril'** and the **'Losartan'** molecules, generic entry brought down unit prices, but not to levels of significance.

Figure 6-14: Relative prices in the Captropril molecule (LE per unit)

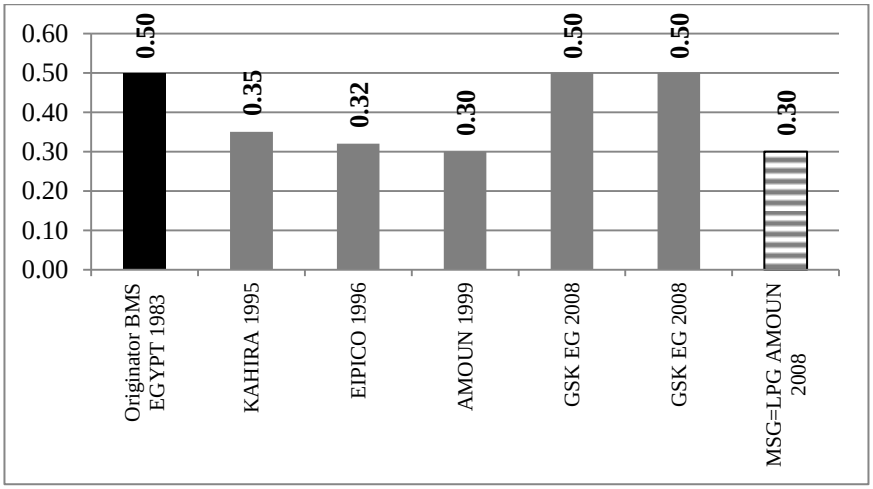
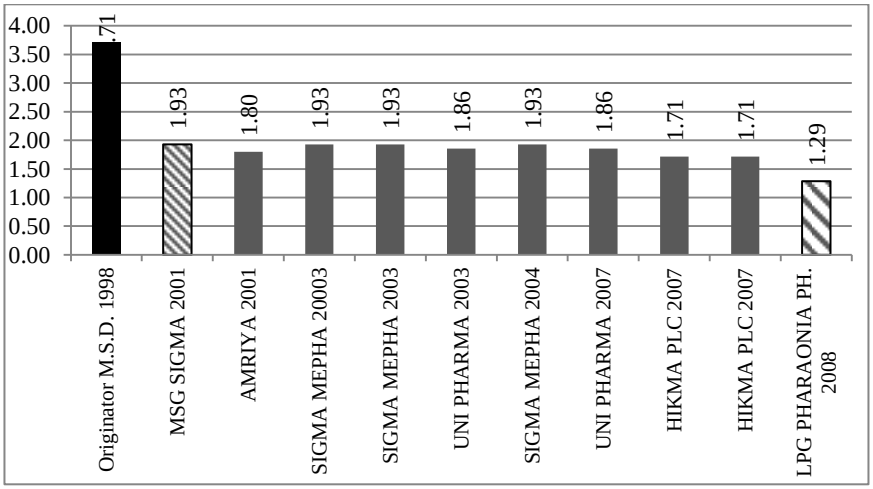
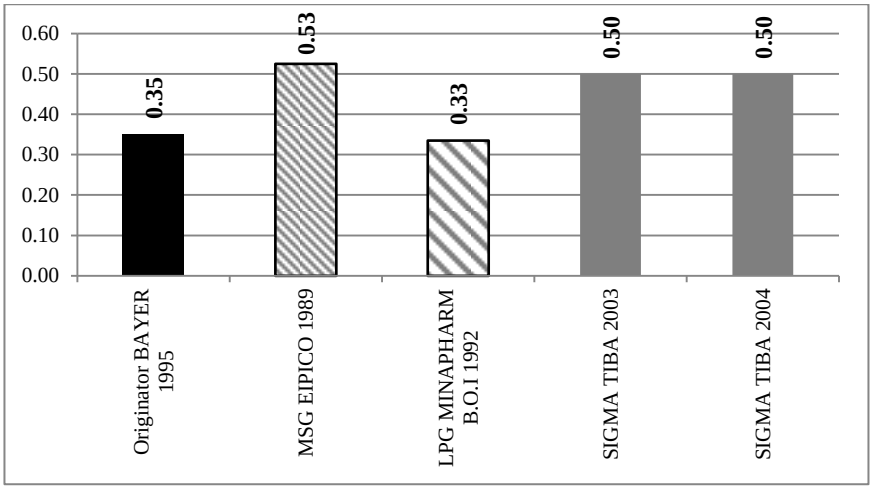


Figure 6-15: Relative prices in the Losartan molecule (LE per unit)



For the **'Nifedipine'** molecule, all generic products which entered the market both prior to and after the entry of the originator band 'Adalat' of Bayer, charged much higher unit prices than the originator.

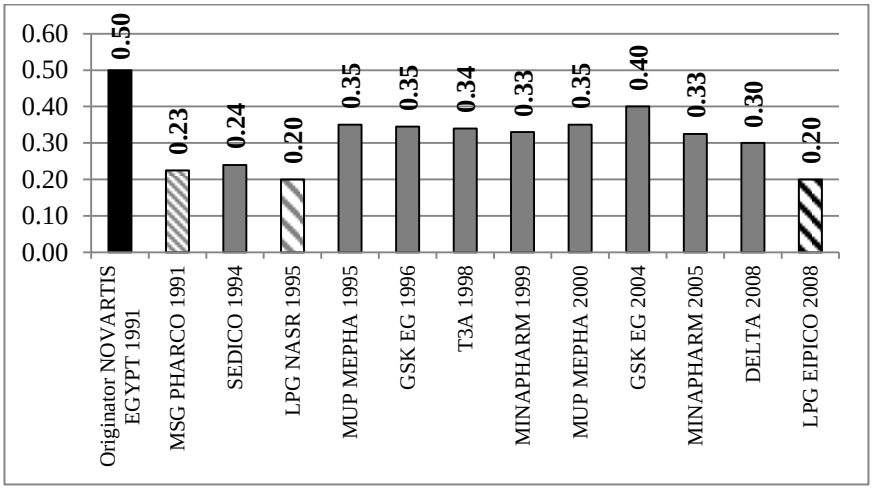
Figure 6-16: Relative prices in the Nifedipine molecule (LE per unit)



Anti-inflammatory: Diclofenac

'Diclofenac' was the key molecule examined on the Egyptian anti-inflammatory market. Diclofenac was approved for marketing in the USA in 1988, when Novartis launched the brand name Voltaren (source). Voltaren was introduced in Egypt by Novartis in 1989, selling at LE 0.38 per unit. The first generic product to enter the market for Dicloenac was Pharco's 'Declophen', which sold at LE 0.23 per unit. A total of 12 competing products entered the market between 1991 and 2008, with the mean unit price standing at LE 0.3 as each new market entrant increased unit prices beyond the level of the previous entrant.

Figure 6-17: Relative prices in the Diclofenac molecule (LE per unit)



Anxiolytic and Serum Lipid Reducing

In both the molecules of **'Diazepam'** and **'Lovastatin'**, only generic companies are present on the market, with no significant reduction in prices for new market entrants for both molecules.

Figure 6-18: Relative prices in the Diazepam molecule (LE per unit)

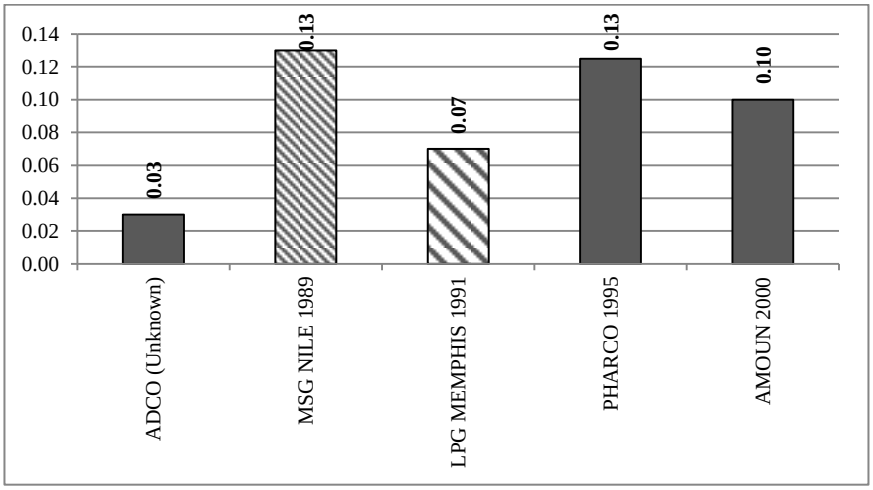
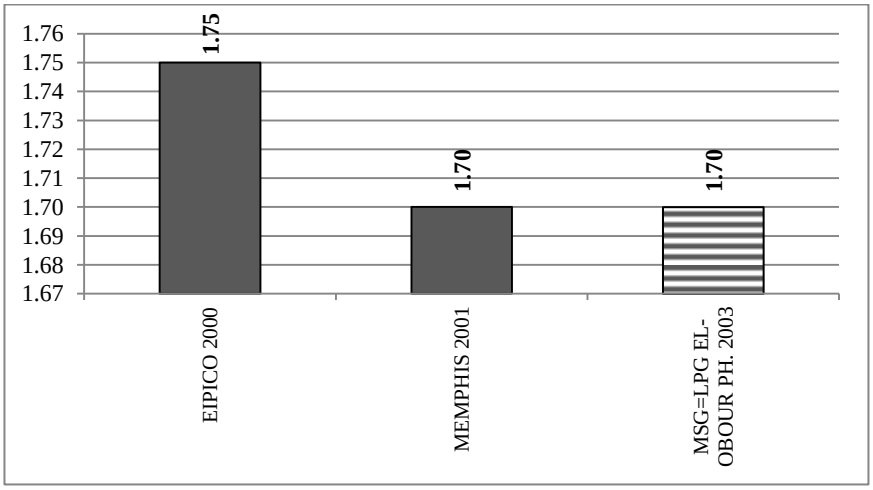


Figure 6-19: Relative prices in the Lovastatin molecule (LE per unit)



A key finding from examining prices in conjunction with the rate of generic diffusion for the sample molecules is that generic diffusion does not significantly bring down average prices on the Egyptian market. With only one exception, for products competing within the domain of the 19 molecules examined, the prices of subsequent market were either clustered around the first entrant, or went above it.

Table 6-3 provides the summary results of the correlation coefficient of the two variables the number of products on the market (starting with the first year a product was launched within the domain of the concerned molecule) and the mean price per unit within each molecule following subsequent generics market entrants for each year up to 2008. In 6 out of the 19 molecules (in which there was significant generic diffusion), there was no evidence of a positive correlation between the increase in the number of generic product within the molecule and the decrease in the mean price per unit following the entry of each subsequent market entrant.

Table 6-3: Correlation coefficient of the two variables the number of products on the market and mean prices

Class/molecule	Number of generic products	Correlation coefficient of number of products on the market starting with the launch of first product and mean price per unit within molecule following each new generic entrant
Antacid		
Omeprazole	17	-0.93
Ranitidine	13	-0.53
Antiasthmatic		
Beclometasone	2	1
Antibacterial		
Amoxicillin	6	0.69
Ceftriaxone	4	-0.05
Ciprofloxacin	4	0.80
Antidepressant		
Fluoxetine	6	-0.86
Antidiabetic		
Glibenclamide	2	-1
Metformin	9	0.31
Antiepileptic		
Carbamazepine	14	0.86
Phenytoin	4	0.97
Antifungal		
Fluconazole	6	0.73
Antihypertensive		
Atenolol	6	0.26
Captopril	4	-0.98
Losartan	10	-0.63
Nifedipine	4	-0.52
Anti-inflammatory		
Diclofenac	12	0.99
Anxiolytic		
Diazepam	4	-0.62

6.7 Have Egyptian Consumers Been Capturing the Financial Benefits From Having Access to Cheaper Generics?

This section attempts to answer the important question of whether or not Egyptian consumers have been fully capturing the financial benefits from having access to *-cheaper-* generics. As indicated in Table 6-2, in the case of the majority of the sample molecules, generics dominated the market, both in terms of volume as well as value shares.

To evaluate the extent to which Egyptian consumers (patients) are capitalizing on the cost advantage of a highly genericised market, the prices and market shares of originator products were compared to those of the most sold generic and the least priced generic within the domain of the study molecule. IMS data provided the necessary information regarding dispensed volumes in the retail (pharmacies) sector, sales value as well as information regarding prices and market shares.

Table 6-4 presents the summary results, which provide evidence that of the 21 study-molecules for which IMS Egypt provided sufficient information, in only 2 cases were the most sold generic also the least priced generic. In half of the molecules examined (10) the single largest product market share has been held by the innovator brand(s). For each of the sample molecules in Table 6-4, the originator product is listed on top raw(s), followed by generic products listed sequentially according to their launch dates.

Table 6-4: Sales by originator brands, least priced generic (LPG) and most sold generic (MSG) on the Egyptian market 2003 and 2008

Class/molecule	Sector	Company	Product	Pack	Launch Year	Sales value (LE 'million)		Public Price LE	Price per unit LE
						2003	2008		
Antacid									
1.OMEPRAZOLE									
Originator	Imported	ASTRAZENECA	LOSEC	ENT.FILM CAP 20 MG 14	1993	0.0	-	140.0	10.00
Originator	Imported	ASTRAZENECA	LOSEC	ENT.FILM CAP 20 MG 7	2003	5.7	2.1	49.0	7.00
	Private	AMRIYA.	GASTRAZOLE	CAPS ENTERIC 20 MG 14	1994	21.14	0.00	42.40	3.03
	Private	EIPICO	EPIRAZOLE	CAPS ENTERIC 20 MG 14	1994	4.80	3.42	44.00	3.14
	Private	PHARCO	ULSTOP	CAPS ENTERIC 20 MG 14	1995	1.86	0.05	42.40	3.03
	Imported	JULPHAR	RISEK	CAPS ENTERIC 20 MG 14	1996	4.0	3.4	40.0	2.86
	Imported	JULPHAR	RISEK	CAPS ENTERIC 20 MG 28	1996	0.5	1.7	75.0	2.68
	Private	AMOUN PHARM.CO.	HYPOSEC	CAPS 20 MG 14	1996	1.2	0.3	42.0	3.00
	Private	MUP MEPHA	GASEC 20	CAPS 20 MG 7	1996	9.0	5.1	22.0	3.14
	Private	PHARCO	ULSTOP	CAPS ENTERIC 20 MG 8	1996	3.8	1.6	24.0	3.00
	Private	MUP MEPHA	GASEC 20	CAPS 20 MG 14	1997	8.4	7.9	37.7	2.69
	Private	SEDICO	OMEPAK	CAPS 20 MG 7	1998	12.6	10.8	16.5	2.36
	Private	AMOUN PHARM.CO.	HYPOSEC	CAPS 20 MG 5	1999	2.2	0.5	15.0	3.00
	Private	SEDICO	OMEPAK	CAPS 20 MG 14	1999	2.9	5.2	33.0	2.36
	Holdipharma	MEMPHIS	OMEPRAL	CAPS 20 MG 14	2000	6.9	6.9	21.0	1.50
MSG	Private	GLOBAL NAPI	NAPIZOLE	CAPS 20 MG 14	2000	14.8	21.7	23.0	1.64
	Private	GLOBAL NAPI	NAPIZOLE	CAPS 20 MG 28	2001	0.1	-	42.0	1.50
	Private	OCTOBER PHARMA	FASTCURE	CAPS 20 MG 7	2004	-	0.4	18.9	2.70
	Private	OCTOBER PHARMA	FASTCURE	CAPS 20 MG 14	2005	-	1.4	24.0	1.71
	Private	EURO.EGY.PH.	GASTRAZOLE	CAPS 20 MG 14	2006	-	15.3	42.4	3.03
LPG	Private	PHARAONIA PH.	OMEZ	CAPS 20 MG 14	2007	-	7.2	13.5	0.96
	Private	UNITED PH.MNF.	OMISEC	CAPS 20 MG 14	2007	-	4.8	42.0	3.00

- Holdipharma is the Drug Holding Company

Cont.

Class/molecule	Sector	Company	Product	Pack	Launch Year	Sales value (LE 'million)		Public Price LE	Price per unit LE
						2003	2008		
Antacid									
2.RANITIDINE									
Originator	MULTINATIONAL	GSK EG	ZANTAC	FILM C.TABS 150 MG 20	1994	31.1	23.2	20.0	1.00
Originator	MULTINATIONAL	G GSK EG	ZANTAC	TABS EFF 150 MG 20	1997	5.2	5.2	24.0	1.20
	PRIVATE SECTOR	MUP	RANITIDINE	C.TAB 150 MG 20	1989	9.4	7.2	12.5	0.63
	PRIVATE SECTOR	SEDICO	RANITAK	FILM C.TABS 150 MG 20	1990	8.2	6.0	14.0	0.70
	HOLDIPHARMA	CID RANBAXY	HISTAC	TABS 150 MG 20	1997	1.2	0.8	13.0	0.65
	HOLDIPHARMA	NASR	RANTIDOL	TABS 150 MG 20	1997	14.1	5.7	9.5	0.48
	HOLDIPHARMA	ADCO	RANTIDINE	TABS 150 MG 10	1998	0.0	0.0	5.0	0.50
MSG	PRIVATE SECTOR	PHARCO	RANI	POWD. EFF 150 MG 6	2000	5.6	20.3	4.0	0.67
	PRIVATE SECTOR	PHARCO	RANICAP	CAPS 150 MG 20	2000	0.5	-	12.5	0.63
	HOLDIPHARMA	ADCO	RANTIDINE	TABS 150 MG 20	2001	0.1	0.1	9.9	0.50
	IMPORTED SECTOR	JULPHAR	RANTAG	TABS 150 MG 20	2003	0.2	0.2	15.0	0.75
	PRIVATE SECTOR	PHARCO	RANI	POWD. EFF 150 MG 60	2007	-	4.2	40.0	0.67
	PRIVATE SECTOR	SIGMA	ACILOC	EFF.GRA.SACH 150 MG 10	2008	-	0.0	6.0	0.60
	PRIVATE SECTOR	SIGMA	ACILOC	EFF.GRA.SACH 150 MG 5	2008	-	0.1	3.0	0.60
	PRIVATE SECTOR	UNI PHARMA	RANIDIL	FILM C.TABS 150 MG 20	2008	-	0.1	9.0	0.45
LPG	PRIVATE SECTOR	UNI PHARMA	RANTIBLOCK	FILM C.CAPS 150 MG 20	2009	-	-	9.0	0.45

Cont.

Class/molecule	Sector	Company	Product	Pack	Launch Year	Sales value (LE 'million)		Public Price LE	Price per unit LE
						2003	2008		
Antiasthmatic									
3.BECLOMETASONE									
Originator	Multinational	GSK EG	BECONASE	SPRAY 50 Y 200	1996	0.0	-	19.0	19.0
MSG	Holdipharma	ADCO CHIESI	CLENIL	INHA.DOSIER 50 Y /DOS 200 15 G	1985	50.0	44.0	16.0	16.0
	Holdipharma	ADCO CHIESI	CLENIL	INHA.DOSIER 50 Y /DOS 200 15 G	1985	50.0	44.0	16.0	16.0
	Private	AMOUN PHARM.CO.	BECLO	NASAL SPRAY 50 Y /DOS 200 20 ML	2006	-	11.9	19.0	19.0
Antibacterial									
4.AMOXICILLIN									
Originator	Private	PHARCO BMS	HICONCIL	CAPS 250 MG 12	1990	16.9	9.6	4.5	0.38
	Holdipharma	CID	AMOXYCID	CAPS 250 MG 12	1980	0.0	-	4.3	0.36
	Private	AMOUN PHARM.CO.	IBIAMOX	CAPS 250 MG 12	1981	18.4	10.0	3.7	0.31
MSG	Private	EIPICO	FLUMOX	CAPS STRIPS 250 MG 12	1985	43.9	75.2	7.5	0.63
	Private	SEDICO	FLUCAMOX	CAPS 250 MG 12	1994	4.1	1.4	6.3	0.53
	Private	SEDICO	BIOMOX	CAPS 250 MG 12	1997	7.6	3.9	5.3	0.44
LPG	Holdipharma	ADCO	AMOXYCILLIN	CAPS 250 MG 12	oooo	9.0	-	2.7	0.23
5.CEFTRIAXONE									
Originator	Holdipharma	KAHIRA SANDOZ	CEFTRIAXONE	V.IM DRY 1 G 1 3.50 ML	2003	22.6	25.3	29.0	29.0
	Private	EIPICO ROCHE	ROCEPHIN	V.IM DRY 1 G 1	1988	37.6	17.8	46.0	46.0
	Private	EIPICO ROCHE	ROCEPHIN	V.IV DRY 1 G 1	1988	14.8	7.0	46.0	46.0
	Holdipharma	CID T3A	CEFOTRIX T3A	V.IM/IV DRY 1 G 1	1998	15.2	1.1	30.0	30.0
	Holdipharma	KAHIRA SANDOZ	CEFTRIAXONE	V.IV DRY 1 G 1 5 ML	2003	9.7	7.9	29.0	29.0
MSG	Private	PHARCO	CEFAXONE	V.IM 1 G 1	2005	-	21.7	20.0	20.0
	Holdipharma	CID RANBAXY	OFRAMAX	V.IM DRY 1 G 1 3.50 ML	2005	-	9.3	22.5	22.5
	Holdipharma	CID RANBAXY	OFRAMAX	V.IV DRY 1 G 1 10 ML	2005	-	1.1	22.5	22.5
LPG	Imported	TABUK PH.	TRIAXONE	V.IV LYOP. 1 G 1 10 ML	2005	-	0.9	35.0	35.0
	Imported	TABUK UNITE.PH.MNF	LONGACEF	V.IM DRY 1 G 1	2007	-	5.0	35.0	35.0
	Imported	TABUK UNITE.PH.MNF	LONGACEF	V.IV DRY 1 G 1	2007	-	1.7	35.0	35.0
	Private	PHARCO	CEFAXONE	V.IV DRY 1 G 1	2008	-	1.0	20.0	20.0

Cont.

Class/molecule	Sector	Company	Product	Pack	Launch Year	Sales value (LE 'million)		Public Price LE	Price per unit LE
						2003	2008		
Antibacterial									
6.Ciprofloxacin									
Originator	Private	HIKMA BAYER	CIPROBAY	FILM C.TABS 500 MG 10	1997	22.8	-	46.0	0.22
	Multinational	NPE SANDOZ	SERVIFLOX	TABS 500 MG 10	1997	13.3	30.1	28.0	0.36
	Private	AMRIYA PHARMACEUT.	CIPROFLOXACIN	FILM C.TABS 500 MG 10	1995	13.4	10.3	30.0	0.33
	Private	MUP MEPHA	BACTIFLOX	FILM C.TABS 500 MG 10	1996	18.6	13.8	31.0	0.32
	Private	EIPICO	CIPROCIN	TABS 500 MG 10	1996	9.6	11.6	32.0	0.31
	Holdipharma	CID RANBAXY	RANCIF	TABS 500 MG 10	1997	2.6	2.8	22.5	0.44
	Holdipharma	MISR	MIFOXIN	TABS 500 MG 10	1997	10.4	7.3	29.7	0.34
MSG	Private	PHARCO	CIPROFAR	TABS 500 MG 10	2002	-	17.3	20.0	0.50
LPG	Imported	SPIMACO	CIPROMAX	FILM C.TABS 500 MG 10	2002	7.7	6.1	33.0	0.30
	Private	EURO.EGY.PH.	CIPROFLOXACIN	TABS 500 MG 10	2006	1.6	0.6	30.0	0.33
	Private	UNI PHARMA	CIPROQUIN	FILM C.TABS 500 MG 10	2008	-	-	15.0	0.67
	Private	EL-OBOUR PH.	CIPROXIL-XL	C.TAB 500 MG 10	2009	-	0.0	18.0	0.56
Antidepressant									
7.AMITRIPTYLINE									
	Holdipharma	KAHIRA	TRYPTIZOL	TABS 10 MG 100	2000	428.2	369.1	5.0	
	Holdipharma	KAHIRA	TRYPTIZOL	TABS 25 MG 30	2000	1,356.2	1,310.2	3.5	
8.FLUOXETINE									
Originator	Imported	ELI LILLY	PROZAC	CAPS 20 MG 14	1996	5.3	2.3	65.0	0.22
Originator	Imported	ELI LILLY	PROZAC	TABS DISPERS 20 MG 7	2002	0.6	-	33.0	0.21
	Holdipharma	MISR	FLUXOTINE	CAPS 20 MG 10	1996	25.9	18.1	15.5	0.65
MSG	Private	AMRIYA PHARMACEUT.	DEPREBAN	CAPS STRIPS 20 MG 10	1998	20.8	21.5	15.2	0.66
	Private	AMOUN PHARM.CO.	PHILOZAC	CAPS 20 MG 10	1999	24.2	40.2	9.0	1.11
LPG	Private	OCTOBER PHARMA	OCTOZAC	CAPS 20 MG 10	1999	3.2	7.9	18.0	0.56
	Private	T3A	FLOROSIN	CAPS 20 MG 10	2001	11.8	7.2	9.0	1.11
	Private	EIPICO	FLUTIN	CAPS 20 MG 14	2003	8.1	2.9	9.2	1.52

Cont.

Class/molecule	Sector	Company	Product	Pack	Launch Year	Sales value (LE 'million)		Public Price LE	Price per unit LE
						2003	2008		
Antidiabetic									
9.GLIBENCLAMIDE									
Originator	Private	GLAXO EG. ROCHE	EUGLUCON	TABS 5 MG 30	1980	9.9	14.5	2.8	0.09
	Multinational	SANOFI AVENTIS EGY	DAONIL	TABS 5 MG 20	oooo	5.2	-	6.0	0.30
	Multinational	CHEMIPHARM	EUGLUMIDE	TABS 5 MG 30	2005	84.9	81.1	6.0	0.20
MSG/LPG	Private	PHARCO	DIABEN	TABS 5 MG 20	1988	-	4.4	2.0	0.10
10.METFORMIN									
Originator	Multinational	NOVARTIS PH. EGYPT	GLUCOFORMIN	TABS 500 MG 20	2002	15.3	12.5	2.0	0.10
	Multinational	NOVARTIS PH. EGYPT	GLUCOFORMIN	TABS 500 MG 80	2002	-	47.1	8.0	0.10
LPG	Holdipharma	NASR	METFORMIN	TABS STRIPS 500 MG 200	0000	6.9	2.5	20.0	0.10
	Holdipharma	CID	CIDOPHAGE	TABS 500 MG 10	1996	0.1	0.3	1.3	0.13
	Holdipharma	CID	CIDOPHAGE	TABS 500 MG 20	1996	0.8	0.6	2.5	0.13
	Holdipharma	CID	CIDOPHAGE	TABS 500 MG 500	1997	0.1	-	62.5	0.13
LPG	Holdipharma	NASR	METFORMIN	TABS 500 MG 30	1999	15.3	1.6	3.0	0.10
	Private	AMOUN PHARM.CO.	AMOPHAGE	TABS 500 MG 10	2000	0.1	-	1.5	0.15
	Private	AMOUN PHARM.CO.	AMOPHAGE	TABS 500 MG 30	2000	24.5	16.1	4.5	0.15
LPG	Private	PHARCO	DIAFORMIN	TABS 500 MG 20	2000	0.0	-	2.0	0.10
LPG	Private	PHARAONIA PH.	DIAPHAGE	TABS 500 MG 20	2001	0.4	1.6	2.0	0.10
MSG	Private	MINAPHARM MERCK	GLUCOPHAGE	FILM C.TABS 500 MG 50	2006	36.4	17.7	15.0	0.30

Cont.

Class/molecule	Sector	Company	Product	Pack	Launch Year	Sales value (LE 'million)		Public Price LE	Price per unit LE
						2003	2008		
Antiepileptic									
11.CARBAMAZEPINE									
Originator	Multinational	NOVARTIS PH. EGYPT	TEGRETOL	TABS C.R 200 MG 20	1991	-	0.5	16.0	0.80
	Multinational	NOVARTIS PH. EGYPT	TEGRETOL	TABS 200 MG 30	2005	-	0.6	16.5	0.55
	Holdipharma	CID	TEGRAL	TABS 200 MG 50	1985	-	0.4	9.5	0.19
LPG	Holdipharma	CID	TEGRAL	TABS 200 MG 10	1985	-	0.0	1.9	0.19
	Multinational	NOVARTIS PH. EGYPT	TEGRETOL	TABS 200 MG 20	1986	-	0.6	11.0	0.55
	Imported	GEROT	NEUROTOP	TABS 200 MG 10	1998	1.1	4.9	3.8	0.38
	Private	PHARCO-T3A	TONOCLONE	F.C.TABS CR 200 MG 10	2000	0.2	0.0	3.3	0.33
	Private	AMOUN PHARM.CO.	CARBATOL	TABS 200 MG 20	2003	72.4	0.0	9.0	0.45
	Imported	GEROT	NEUROTOP	TABS 200 MG 100	2004	-	1.7	55.0	0.55
	Private	PHARCO-T3A	TONOCLONE	F.C.TABS CR 200 MG 20	2004	-	0.3	5.0	0.25
	Private	UNI PHARMA	MAZEMAL	TABS 200 MG 20	2005	26.4	28.3	8.5	0.43
MSG	Private	UNI PHARMA	MAZEMAL	TABS 200 MG 50	2007	-	62.2	21.3	0.43
	Private	T3A	TONOCLONE	TABS C.R 200 MG 10	2007	-	0.0	2.5	0.25
	Imported	MULTIAPEX PH.	CARBAPEX	TABS C.R 200 MG 30	2008	-	0.4	22.5	0.75
	Imported	MULTIAPEX PH.	CARBAPEX	TABS 200 MG 30	2008	0.0	-	18.0	0.60
12. PHENYTOIN									
Originator	Holdipharma	NILE PFIZER	EPANUTIN	TABS 100 MG 100	2000	0.0	-	10.0	0.10
Originator	Holdipharma	NILE PFIZER	EPANUTIN	CAPS 100 MG 100	1995	0.1	-	10.0	0.10
Originator	Private	NILE PFIZER	EPANUTIN	CAPS 50 MG 100	1995	-	9.1	5.0	0.05
	Holdipharma	ALEXANDRIA BAYER	COMITAL L	TABS 100	2000	17.1	0.9	15.0	
	Holdipharma	NILE PFIZER	EPANUTIN	CAPS 100 MG 50	2000	0.0	-	12.0	0.24
LPG	Holdipharma	NASR	PHENYTOIN	CAPS 100 MG 40	1998	62.0	0.8	5.8	0.15
	Holdipharma	NILE	PHENYTIN	A.IM 100 MG 1 2 ML	2004	-	-	2.3	
	Holdipharma	NILE	PHENYTIN	A.IM 100 MG 10 2 ML	2004	20.8	7.3	22.5	
MSG	Holdipharma	NILE	PHENYTIN	CAPS 100 MG 50	2004	-	68.6	12.0	0.24
	Holdipharma	ARAB GELAT.ACDIMA	IPANTEN	CAPS 100 MG 50	2005	-	0.2	16.0	0.32
	Holdipharma	MEMPHIS	PHENYTOIN	CAPS 100 MG 50	2006	-	5.0	14.0	0.28
	Holdipharma	ALEXANDRIA	COMIDAL-L	TABS 100	2008	-	8.1	40.0	

Cont.

Class/molecule	Sector	Company	Product	Pack	Launch Year	Sales value (LE 'million)		Public Price LE	Price per unit LE
						2003	2008		
Antifungal									
13.FLUCONAZOLE									
Originator	Multinational	PFIZER EGYPT	DIFLUCAN	CAPS 150 MG 1	1993	33.0	31.5	27.0	27.00
LPG/MSG	Private	SEDICO	FLUCORAL	CAPS 150 MG 2	1996	37.9	29.3	14.6	7.30
	Private	HIKMA PLC	ALKANAZOLE	CAPS 150 MG 1	1998	2.6	1.9	14.7	14.70
	Private	RAMEDA T3A	TRICONAL	CAPS 150 MG 1	1998	5.3	2.1	14.7	14.70
	Private	AMOUN PHARM.CO.	FUNGICAN	CAPS 150 MG 1	2001	14.6	17.1	10.0	10.00
	Private	EIPICO	TREFLUCAN	CAPS 150 MG 1	2002	6.7	16.1	8.0	8.00
	Imported	SPIMACO	FLOCAZOLE	CAPS 150 MG 1	2006	-	2.0	18.0	18.00
Antihypertensive									
14.ATENOLOL									
Originator	Holdipharma	KAHIRA ASTRAZENECA	TENORMIN	TABS 50 MG 14	1993	69.6	1.0	6.6	0.47
Originator	Imported	ASTRAZENECA EGYPT	TENORET	FILM C.TABS 50 MG /12 14	2007	-	1.9	9.0	0.64
Originator	Imported	ASTRAZENECA EGYPT	TENORMIN	FILM C.TABS 50 MG 14	2007	7.8	14.9	8.0	0.57
LPG	Private	MUP PRODES	BLOKIUM	TABS 50 MG 15	1993	-	0.1	5.0	0.33
	Private	EIPICO	ATENO	TABS 50 MG 20	1998	-	0.6	3.3	0.16
	Private	SIGMA	TENEDONE	TABS 50 MG 20	2000	-	0.5	11.0	0.55
	Imported	JEDCO	ATENOLOL	TABS 50 MG 20	2004	7.7	13.8	4.3	0.31
	Private	PHARCO	ATELOL	TABS 50 MG 20	2004	14.9	14.3	3.5	0.18
MSG	Holdipharma	KAHIRA	TENOTENS	TABS 50 MG 14	2008	-	52.8	6.0	0.43

Cont.

Class/molecule	Sector	Company	Product	Pack	Launch Year	Sales value (LE 'million)		Public Price LE	Price per unit LE
						2003	2008		
Antihypertensive									
15.CAPTOPRIL									
Originator	Multinational	BMS EGYPT	CAPOTEN	TABS 25 MG 40	2003	56.4	0.0	20.0	0.50
Originator	Multinational	BMS EGYPT	CAPOTEN	TABS 25 MG 20	1983	0.6	0.4	10.0	0.50
	Holdipharma	KAHIRA	LONTENSIN	TABS 25 MG 20	1995	-	12.2	7.0	0.35
	Private	EIPICO	CAPOTRIL	TABS 25 MG 20	1996	1.9	1.3	6.4	0.32
	Private	AMOUN PHARM.CO.	HYPOPRESS	TABS 25 MG 10	1999	-	0.1	3.0	0.30
	Multinational	GLAXOSMITHKLINE EG	CAPOTEN	TABS 25 MG 20	2008	28.9	67.1	10.0	0.50
	Multinational	GLAXOSMITHKLINE EG	CAPOTEN	TABS 25 MG 40	2008	-	-	20.0	0.50
LPG/MSG	Private	AMOUN PHARM.CO.	HYPOPRESS	TABS 25 MG 30	2008	12.3	18.9	9.0	0.30
	Private	PHARAONIA PH.	ANGIOPRESS	TABS 25	2009	-	-	3.0	
16.LOSARTAN									
Originator	Imported	M.S.D.	HYZAAR	TABS 50 MG 14	1998	56.9	45.2	52.0	3.71
Originator	Imported	M.S.D.	COZAAR	TABS 50 MG 14	1998	-	1.7	52.0	3.71
MSG	Private	SIGMA	LOZAPRESS	TABS 50 MG 14	2001	31.7	29.8	27.0	1.93
	Private	AMRIYA PHARMACEUT.	LOSARTAN	TABS 50 MG 10	2001	0.0	0.0	18.0	1.80
	Private	SIGMA MEPHA	LOSARMEPHA	TABS 50 MG 14	2003	8.5	12.3	27.0	1.93
	Private	SIGMA MEPHA	LOSARMEPHA	TABS 50 MG 7	2003	-	1.2	13.5	1.93
	Private	UNI PHARMA	LOSAR	TABS 50 MG 7	2003	0.4	-	13.0	1.86
	Private	SIGMA MEPHA	LOSARMEPHA PLUS	TABS 50 MG /12 7	2004	-	1.3	13.5	1.93
	Private	UNI PHARMA	LOSAR	TABS 50 MG 28	2007	-	0.1	52.0	1.86
	Private	HIKMA PLC	KANZAR-H	FILM C.TABS 50 MG /12 7	2007	1.4	2.7	12.0	1.71
	Private	HIKMA PLC	KANZAR	TABS 50 MG 7	2007	-	0.3	12.0	1.71
LPG	Private	PHARAONIA PH.	LOSARTAN	TABS 50 MG 14	2008	1.1	5.4	18.0	1.29

Cont.

Class/molecule	Sector	Company	Product	Pack	Launch Year	Sales value (LE 'million)		Public Price LE	Price per unit LE
						2003	2008		
Antihypertensive									
17.NIFEDIPINE									
Originator	Holdipharma	ALEXANDRIA BAYER	ADALAT	TABS 20 MG 30	1995	37.1	-	10.5	0.35
MSG	Private	EIPICO	EPILAT	TABS L.A 20 MG 20	1989	84.5	80.3	10.5	0.525
LPG	Private	MINAPHARM B.O.I	DILCOR	CAPS L.A 20 MG 20	1992	0.0	-	6.7	0.335
	Private	SIGMA TIBA	TENOLAT	CAPS S.R 20	2003	2.8	19.6	10.0	0.5
	Private	SIGMA TIBA	TENOLAT	CAPS S.R 30	2004	-	0.1	15.0	0.75
Anti-inflammatory									
18.DICLOFENAC									
Originator	Multinational	NPE NOVARTIS C.H.	VOLTAREN C.H.	ENTER.C.TABS 25 MG 30	1989	11.1	8.3	11.3	0.38
Originator	Multinational	NOVARTIS . EGYPT	CATAFLAM	C.TAB 25 MG 10	1991	43.0	0.0	5.0	0.50
Originator	Multinational	NOVARTIS EGYPT	CATAFLAM	C.TAB 25 MG 20	2005	-	53.7	10.0	0.50
MSG	Private	PHARCO	DECLOPHEN	TABS 25 MG 20	1991	15.1	8.4	4.5	0.23
	Private	SEDICO	RHEUMARENE	TABS 25 MG 20	1994	3.0	2.4	4.8	0.24
LPG	Holdipharma	NASR	DICLOFENAC	TABS 25 MG 30	1995	2.1	1.2	6.0	0.20
	Private	MUP MEPHA	OLFEN	LACTABS 25 MG 30	1995	7.9	7.1	10.5	0.35
	Multinational	GLAXOSMITHKLINE EG	RHEUMAFEN	C.TAB 25 MG 20	1996	2.4	1.0	6.9	0.35
	Private	T3A	ANTIFLAM	TABS 25 MG 10	1998	7.1	2.7	3.4	0.34
	Private	MINAPHARM TOP PHAR	POTAFEN	TABS 25 MG 10	1999	1.1	0.0	3.3	0.33
	Private	MUP MEPHA	OFLAM	TABS 25 MG 10	2000	7.2	6.4	3.5	0.35
	Multinational	GLAXOSMITHKLINE EG	RAPIFLAM	TABS 25 MG 10	2004	-	3.8	4.0	0.40
	Private	MINAPHARM TOP PHAR	POTAFEN	TABS 25 MG 20	2005	-	1.3	6.5	0.33
	Private	DELTA	DOLPHIN-K	TABS 25 MG 20	2008	-	1.6	6.0	0.30
LPG	Private	EIPICO	EPIFENAC	TABS 25 MG 20	2008	-	2.2	4.0	0.20

Cont.

Class/molecule	Sector	Company	Product	Pack	Launch Year	Sales value (LE 'million)		Public Price LE	Price per unit LE
						2003	2008		
Antiviral									
19.Acyclovir									
Originator	Multinational	GLAXOSMITHKLINE EG	NOVIRUS	CAPS 200 MG 8	1994	72.4	74.9	11.0	1.38
Originator	Multinational	GLAXOSMITHKLINE EG	ZOVIRAX	TABS 200 MG 25	1986	0.2	-	166.8	6.67
	Private	SEDICO	CYCLOVIRAL	TABS 200 MG 20	1997	27.3	25.1	21.0	1.05
Anxiolytic									
20.DIAZEPAM									
	Holdipharma	ADCO	CALIUM	TABS 5 MG 20	0000	5.1	-	0.6	0.03
MSG	Holdipharma	NILE	VALINIL	TABS 5 MG 10	1989	72.6	85.3	1.3	0.13
LPG	Holdipharma	MEMPHIS	NEURIL	TABS 5 MG 10	1991	20.6	6.5	0.7	0.07
	Private	PHARCO	FARCOZEPAM	TABS 5 MG 20	1995	-	0.3	2.5	0.13
	Private	AMOUN PHARM.CO.	VALPAM	TABS 5 MG 10	2000	1.6	7.9	1.0	0.10
Serum lipid reducing									
21.LOVASTATIN									
	Private	EIPICO	LOWCHOL	TABS 20 MG 10	2000	2.2	-	17.5	1.75
	Holdipharma	MEMPHIS	LOVASTAN	TABS 20 MG 10	2001	67.4	-	17.0	1.70
MSG	Private	EL-OBOUR PH.	CHOLILYSIS	TABS 20 MG 10	2003	30.4	100.0	17.0	1.70

6.8 Summary and Conclusion

In this chapter, I have attempted to provide an answer to the research question concerning how far and in what ways have the regulatory framework governing Egypt's generics pharmaceutical industry allowed local companies to charge higher than average prices compared to other world markets. Three key concerns have been driving the investigation in this Chapter. First, are generic-to-originator drug prices in Egypt in line with the standard ratios in major world markets. Second, has generic diffusion been bringing down average pharmaceutical price levels in Egypt? Third, within the context of an IPRs regime which excluded pharmaceutical products from patentability up to January 2005, have Egyptian consumers been fully capturing the financial benefits of having access to cheap generics?

In order to address the research question, I have relied on the methodology followed by the WHO and HAI (2006) concerned with the international comparison of the prices of chronic disease medicines. The IMS Egypt database provided the main source of data.

The examination of price competition on Egypt's pharmaceutical market has brought up some concerns about generic-to-originator price levels in Egypt for the sample molecules. Evidence has been presented that generic-to-originator prices in Egypt are higher than the standard ratios observed in major world markets. Of no less importance, generic diffusion has not necessarily been bringing down average prices on the Egyptian market for the sample study molecules. In close connection to the review presented in Chapter Four, these results indicate that pricing policies in Egypt need to be revised to induce a visible downward trend regarding relative prices for new generics market entrants, similar to observed patterns in major world markets. The results also indicate that the levels of profit generated by local companies in association with higher than standard generic-to-originator prices for the sample molecules are likely to be high.

On another important front, Egyptian consumers have not been fully capturing the financial benefit of having access to a large generics manufacturing base, particularly in light of a lax IPRs regime which ruled up to January 2005. Prescribing habits have resulted in a situation

whereby the least priced generics are not necessarily the most prescribed. The nature of prescribing norms have to be influenced in a way that entices prescribing physicians to prescribe by generic name, and dispensing pharmaceutics to be able to dispense the lowest priced generic. Inducing such change in prescribing habits should elevate some of the financial burden falling on the uninsured segment of the population that is obliged to cover its needs for drugs out-of-pocket.

The evidence presented threw light on the pressing need to revisit generics policies as well as prescribing practices in Egypt as detailed in Chapter Four. This need is made all the more pertinent, in light of the exerted upward pressure on prices as a result of enforcing pharmaceutical product patent protection in Egypt, as will be detailed in Chapter Seven.

7. What Has Been the Nature and Scope of Impact of the TRIPS Agreement on Pharmaceutical Price Levels in Egypt and on Market Shares of Key Players?

7.1 Introduction

This chapter will attempt to provide an answer to the research question concerned with the impact of strengthening the country's IPRs regime in conformity with the TRIPs Agreement on pharmaceutical price levels in Egypt, as well as the market shares of key players.

This chapter probes deeper into the costs associated with enforcing pharmaceutical product patent protection in Egypt as of January-2005. Costs are narrowed down to the differential between what consumers actually pay for new originator products -which are protected by patents- and what they would have incurred in terms of prices and cost had generic products been available.

This chapter takes the first attempt in Egypt to quantify the impact of the TRIPS Agreement on the country's pharmaceutical market by focusing the analysis on the extent to which Egyptian consumers have been willing to trade-off lower prices of older drugs, for more innovative new products, as well as on how this varies across different therapeutic classes. To date, no attempt has been made to evaluate the nature and magnitude of impact of the TRIPS Agreement on Egypt's pharmaceutical sector using real market data, and hence this chapter contributes to the debate surrounding the TRIPS Agreement with the support of empirically grounded findings. This chapter relies on proprietary data concerning a selection of therapeutic classes from IMS in order to examine pharmaceutical market dynamics in Egypt during the period 2004-2008. The 42 therapeutic classes account for 50 percent of the market by value.

Survey results which covered 25 of Egypt's key players on the pharmaceutical manufacturing scene, including public business sector companies, local generics manufacturers and subsidiaries of research-based pharmaceutical companies concerning

their forecast regarding the impact of the TRIPS Agreement on their business will also be presented. The survey was conducted in April 2004, almost one year before the enforcement of the 20-year period of pharmaceutical patent protection in Egypt. By comparing the survey results to actual market dynamics after January 2005, we will be able to evaluate the degree of precision firms operating on Egypt's pharmaceutical manufacturing scene have had regarding their state of business after the enforcement of pharmaceutical patent protection, and accordingly, the effectiveness of their survival strategies.

The results have indicated that the cost-related impact of the TRIPS Agreement in the domain of Egypt's top 42 therapeutic classes by market value has been put in the range of LE 479 million. Results indicated that in 13 of these top 42 therapeutic classes, there was evidence regarding launches of new molecules by research-based pharmaceutical companies on the Egyptian market, with no evident generic competition.

Shifts in terms of consumer/prescribing physician's preference in favour of new versus mature molecules has, nonetheless, been evident. Such a shift has not yet been reflected in a full-fledged movement in market shares to the disadvantage of local companies. In fact the local private sector has been gaining market shares at a remarkably agile fashion.

Survey results have indicated that most of the perceptions regarding the future state of the business following full respect of pharmaceutical product patent protection in Egypt as reflected in the responses of the various players have suffered from flaws in judgment.

This chapter is structured as follows. Section 7.2 presents the review of the literature to which the empirical findings of this chapter endeavour to contribute to. This literature covers the key developments which led to the inclusion of IPRs issues on the agenda of the Uruguay Round (UR) and the eventual global harmonisation of IPRs. Section 7.3 presents a brief overview of the operation of Egypt's pharmaceutical manufacturers under the framework of the pre-TRIPS IPRs regime. Section 7.4 presents the empirical strategy to answer the questions posed. Section 7.5 quantifies the impact of the TRIPS Agreement on

Egypt's pharmaceutical market. Section 7.6 presents the survey findings. Section 7.7 presents the summary of findings and conclusion.

7.2 The Uruguay Round and the Global Harmonisation of IPRs

The UR of multilateral trade negotiations, which was launched in Punta del Este in 1986, and ended eight years later in Marrakech, provided -*for the first time ever*- the framework for negotiating a global agreement on IPRs. The TRIPS Agreement, together with the Agreement on Trade Related Investment Measures (TRIMs) and the General Agreement on Trade in Services (GATS) have become the main pillars of the WTO, the new international trade bureaucracy which came into force in January 1995, replacing the General Agreement on Tariff and Trade (GATT). The TRIPS Agreement has, therefore, become the first comprehensive multilateral accord to establish *unconditional* obligations for all WTO members on IPRs policies with regard to copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, and trade secrets (Stegemann, 2000:1237).

The World Intellectual Property Organisation (WIPO), which is one of the UN agencies, has managed the pre-TRIPS global IPRs system, which consisted of highly variable IPRs laws and enforcement measures across countries, as well as a set of international treaties. The most notable agreements that fell under the jurisdiction of WIPO were the Paris Convention (1883) for the protection of industrial property and the Bern Convention (1886) for the protection of artistic and literary property. These conventions were, nonetheless, concluded by a relatively small number of counties and were not comprehensive in coverage and enforceability (Maskus, 2000). One of the major drawbacks of the system administered by WIPO was the lack of a dispute settlement mechanism, which promoted unilateral actions by countries defending the interests of their patent and copyright dependent industries.

While former rounds of GATT negotiations have traditionally been restricted to trade issues, patent as well as copyright dependent industries, foremost among which has been the pharmaceutical industry, lobbied extensively to bring IPRs to the forefront during the

UR negotiations. At the onset of the UR in 1986, only a few months following its launch, the President of the US Pharmaceutical Manufacturers Association stated that the industry was working closely with Congress to get it to strengthen the hand of the US government in urging trading partners to respect the industry's rights in inventions and trademarks (Finger and Nogues, 2001). The inclusion of IPRs issues on the UR Agenda was, therefore, largely owed to the *insistences* of US firms whose profits have been eroded by infringing activities elsewhere in the world, particularly in terms of competition with what has been coined as 'pirate firms' in third country markets (Deardorff, 1990, 497).

The USA, led the league of developed countries which were dissatisfied with the *-absence of an-* international system of IPRs and the subsequent losses incurred by patent and copy right dependent industries. It was the United States that played *the* critical role in introducing the issue of IPRs into the deliberations on global trade rules during the UR. The USA framed the case along lines the traditional argument that the net transfer from consumers in developing country markets in the form of royalty payments and increased imports of IPRs intensive products and services, will be compensated by an increase in FDI flows into developing country markets. Of no less importance was the argument that better protection for IPRs in foreign (mainly developing and newly industrialised) countries, was to be exchanged for improving and securing access to developed countries import markets (Stegemann, 2000, 1238-41). On a more substantive and immediate front, the real gain perceived by developing countries from their participation in the UR and the concessions on IPRs was reaching an agreement on phasing out the Multi-Fibre Arrangement (MFA) and the success in bringing agriculture into the GATT/WTO (Krueger, 1999).

The years which followed the creation of the WTO and the transitional enforcement of the TRIPS Agreement by member countries, however, proved to be highly eventful, casting considerable doubt on the validity of the initial assumptions of the mutual benefits of a harmonised IPRs regime to all countries, developed and developing alike.

7.2.1 Lobbying by patent-dependant industries

The TRIPS Agreement represented a major point of departure for national IPRs policies and the global harmonisation of IPRs. The Agreement mandated WTO member countries to set up mechanisms for enforcing stronger IPRs, thus forming the 'vanguard' of efforts to establish deep integration of domestic regulatory policies on a global level (Maskus, 2000).

While most countries members of the former GATT showed no interest in extending the scope of the negotiations beyond traditional trade issues, for the USA the inclusion of IPRs issues 'was a fundamental requirement for .. participation in the talks' (Bradley, 1987, 57). Corporations with strong interest in patent and copyright issues in the USA lobbied the Congress and Administration (the president) to shape the intellectual-property diplomacy of the USA prior to and during the UR (Maskus, 2000).

The USA has often resorted to unilateral retaliation against countries which were judged to provide heavens for infringing industries, using Section 301 of the US Trade Act of 1974,[23] which stipulated that the failure of a foreign country to protect intellectual property adequately is an 'unreasonable practices' that could cause a United States Trade Representative (USTR) investigation and subsequent trade sanctions (retaliation). The so-called Special 301 process mandated the USTR each year to identify foreign countries denying effective protection for intellectual property rights, to be followed by an agenda for intervention (Stegemann, 2000, 1239). Intervention is a synonymous word for trade sanction.[24] Target countries for the Special 301 actions have mainly been developing or newly industrialised countries. The USTR has used the 'Section 301' status of the Trade Act to classify countries in accordance with the strength of their IPRs regimes. Countries with the weakest IPR industry wide, are classified as 'Priority Foreign Countries'. Those with a slightly better protection are considered to be 'Priority Watch Countries', while

[23] The Trade Act of 1974 was amended by the 1984 Trade and Tariff Act and the 1988 Omnibus Trade and Competitiveness Act.

[24] Egypt has frequently appeared on the list of 'Priority Watch Countries', and so have Brazil, Argentina and India (http://www.ustr.gov/reports/2002/special301.htm. Egypt has been moved from the Priority Watch List to the Watch List in 2003 following the enactment of a TRIPS consistent IPRs laws (USTR, 2006).

those, which only need to be monitored for progress, are placed on the 'Watch List' (Rozek and Berkowitz, 1998, p.4).

The following section presents a synopsis of the TRIPS Agreements, bringing to the forefront the various Articles, which pertain to the operations of the pharmaceutical industry.

7.2.2 The TRIPS Agreement

According to the text of the TRIPS Agreement, the logic of the Agreement is mainly build on the assumption that the 'protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual *advantage of producers and users* of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'. Investigating the relationship between investing in R&D and the strength of a country's IPR regime actually provides conflicting evidence. On one hand, utilising a cross-country panel of 32 countries during the period 1981-90, Evenson and Kanwar (2001) provide evidence of a strong positive association between a country's protection of IPRs and the level of R&D investments. They conclude that "the evidence unambiguously indicates the significance of IPRs as incentives for innovation". On the other hand, Branstetter (2004) reviewed several empirical studies undertaken by economists to evaluate the validity of the claim that strengthening IPRs systems induces higher levels of innovation by local firms, and indicated that most studies reviewed actually fail in providing evidence of a strong positive response by domestic innovators that could be correctly attributed to the effect of stronger IPRs. The same study indicated that the impact of stronger IPRs are more likely to occur instead from the acceleration in the domestic deployment of advanced technology by the affiliates of foreign firms.

Advocates of the TRIPS Agreement have argued that while it will result in significant revenue transfers from consumers in developing countries to industrial country producers in the form of royalty payments, in return, developing countries will themselves become attractive locations for FDI. This assumption finds root in the literature linking the major

determinants of FDI in patent dependent industries to the strength of the IPRs regime in host countries (Rozek and Berkowitz, 1998; Rapp and Rozek 1990; Redwood, 1995). Reality, however turned out to be less favourable, as the immediate cost to developing countries as a result of adopting new domestic regulations in areas such as IPRs and the expected increase in the prices of in patent products has been more tangible than the benefits side which is yet to be secured (Finger and Nogues, 2001). Proponents of IPRs protection have also argued that a globally harmonised regime will enhance the international dissemination of ideas, as owners of patents will be encouraged to disclose their inventions. While knowledge will be disseminated more freely, it is the use of knowledge that will be restricted (Deardorff, 1990, 497). The initial assumption of a win-win situation may hold in certain domains of technology, but it has provoked an unresolved debate in the sphere of pharmaceutical production. Of particular concern were those aspects of the Agreement related to the issue of access to and prices of new pharmaceutical products. Because the TRIPS Agreement restricted access on the basis of commercial considerations, a feared consequence was that higher prices for pharmaceuticals and other health care inventions will eventually prevent low-income consumers in the developing world from obtaining life-saving drugs at affordable prices (Lanoszka, 2003).

Terms of protection

The terms of protection awarded to patent holders is standard to a 20-year period of patent protection from the filing date (Part II, Section 5: Patents, Article, 33). The Agreement confers exclusive rights to patent owners and prevents "third parties not having the owner's consent from the actions of: making, using, offering for sale, selling, or importing for those purposes that product" (Part II, Section 5: Patents, Article 28). This Article has significant 'trade related' implications, as it not only prohibits the working of active patents, but extends beyond manufacturing to prohibiting the importation of patent-infringing products into any of the WTO member countries.

WTO member country classifications

The Agreement classified WTO member countries into four major categories; developed (industrialised) countries; countries in transition (mainly in Eastern Europe), developing

countries and least developed counties. Each group was subjected to a set of enforcement dates and transitional arrangements (Part VI, Article 65).[25]

Thirteen WTO members have opted for the longer transitional period, and have indicated that they will not grant patent protection to pharmaceutical products before January 2005. These countries were Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay. Some of these countries have significant generics pharmaceutical production capacities, most notably, India, Brazil and Egypt.

Transitional arrangements

Part VII of the TRIPS Agreement stipulates the introduction of institutional arrangements (Article 70) by countries, which opt for a longer transition period. Countries which do not provide patent protection for pharmaceutical and agricultural chemical products have been obliged to "provide as from the date of entry into force of the TRIPS Agreement a means by which application for patents for such inventions can be filed" (The TRIPS Agreement, Part VII, Article 70). This stipulation has come to be commonly named the 'mailbox'.

The mailbox provision

The idea of a 'mailbox' is that a country that chooses to delay the introduction of patent protection for pharmaceutical products will have to provide a mechanism of accepting patent applications for inventions which were patented after the Agreement came into force in January 1995. These patent applications will reside unprocessed in this 'mailbox' until this country introduces a TRIPS consistent patent law for pharmaceuticals. Patents for products which were in the mailbox are then granted as if they have been in effect since the Agreement came into force. The patent is therefore enforced for the remaining duration of what is left of the standard 20-year period of patent protection.

[25] All WTO member countries were given a period of up to one year following the date of entry into force of the WTO (January 1995) until 1 January 1996 for full enforcement of the TRIPS Agreement. Developing countries were entitled to a delay of a period of up to four years i.e. to January 2000 to apply the provisions of the Agreement. Members in the process of a transformation from a 'centrally-planned into a market, free-enterprise economy' may also benefit from a delay of four years. As for the least developed countries, they were granted a longer transition period of a total of eleven years until January 2005, with the possibility of an extension.

Exclusive marketing rights

In addition to the mailbox obligation, all WTO Member countries (developed and developing countries alike) are obliged to provide marketing exclusivity for drugs whose patent application dates after 1995, for a period of five years (TRIPS Agreement, Part VII, Article 70). During this five-year period, exclusive marketing rights (EMRs) are obtained after a product is granted marketing approval in that member or until a product patent is granted or rejected.

7.2.3 Difficulties in reaching a global consensus regarding the importance of the global harmonisation of IPRs

There was a consensus that when the UR ended, newly industrialised, developing and transition countries would not have accepted the TRIPS Agreement had it stood by itself (Martin and Winters, 1996).

Reaching closure on a harmonized global system of IPRs in 1994 did not necessarily indicate that conformity was reached between WTO member countries with regards the importance of a stronger global IPRs regime and the expected mutual benefits to ensue. In other words, each of the WTO member countries accepted all of the UR agreements as a 'single undertaking'. The TRIPS Agreement being part of the WTO membership *package*, applied to all member countries regardless of their enthusiasm for commitments to be made in the field of IPRs. Flattening enthusiasm on behalf of developing countries, which were obliged to accept the WTO Agreements as a single undertaking began to surface as the various transitional obligations came into force.[26] The ability of developing countries to

[26] Several disputes have erupted between governments of developing countries and the research-based pharmaceutical industry. The most publicized of these disputes has been the case filed by the USA against the Brazilian government with the WTO, for issuing a compulsory licensing for the HIV/AIDS drug whose patent is held by Roche. Almost a year after in June 2001 did the USA agreed to end the trade dispute with Brazil. The trade-off was that the Brazilian government agreed to consult with the US before resorting to compulsory licensing in the future (Reuters, 2001). Of no less importance has been the case raised by 29 pharmaceutical firms against the South African government, over importing generic versions of HIV/AIDS drugs from abroad (mainly from Brazil, Thailand and India). The pharmaceutical companies then dropped the lawsuit, which was raised in South Africa to stop the authorities from importing various generic versions of the drugs (Capella, 2001).

have access to medicine at affordable prices has by far been the most pertinent issue invoked during the implementation of the TRIPS Agreement.

From Marrakech onwards: Singapore, Geneva, Seattle, Doha and Cancun

WTO member countries have agreed in Marrakech on a 'built-in-agenda' which specified future dates for the continuing review/negotiations of specific sectors and subject areas. Officially, a WTO Ministerial Conference should convene at least once every two years, and this is the opportunity for member countries to place their most pertinent issues on the agenda.

The first Ministerial Conference was held in Singapore, December 1996. However, it was relatively early for the TRIPS Agreement to be featured on the agenda.

Seattle, 1999 came as a setback to the WTO member countries that were hoping to launch the Millennium Round. Not only was there failure to launch a new round, but the meeting ended with the WTO facing considerable criticism from many areas, particularly in terms of accommodating the needs of developing countries (Sampson, 2000). The failure of the Seattle meeting meant that most/all of the issues proposed in relations to the TRIPS Agreement were to be postponed to a following meeting.

The Fourth Ministerial Conference which was held in Doha, November 2001 was hailed to have brought "an end the uncertainty, loss of momentum and lack of confidence created by the frustrating failure at Seattle two years earlier". The launch of a new round of multilateral trade negotiations was coined as a "turning-point in the history of the WTO and in relations between developed and developing countries" (WTO, 2002). The true turning point from the perspective of developing countries members of the WTO came with the Doha Declaration on the TRIPS Agreement and Public Health, which was adopted on November 14, 2001.

The Doha declaration on the trips agreement and public health

The Doha Declaration on the TRIPS Agreement and Public Health came against a background of evidence regarding the fact that harmonised IPR standards sharply curtailed the traditional capacity of suppliers of some of the public goods, such as in the case of health care to properly address priority needs of the less affluent members of society, particularly in the case of developing countries. In connection to the Doha Declaration, the Waiver Decision of 30 August 2003, and Article 31bis Protocol of Amendments have re-opened the door for policy intervention in terms of supplying new pharmaceutical products against the relatively restrictive elements of the TRIPS Agreement (Abbott, 2007). The Doha Declaration also mandated further negotiations on one important subject provided in Paragraph 6 "We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem (Abbott, 2007: 317).

The Doha declaration on the TRIPS Agreement and public health came to be very much in favour of developing countries, and was in fact the first acknowledgment by the WTO of the potential adverse 'effects on prices' of the enforcement of higher standards of IPRs in the domain of pharmaceutical production in developing countries (WTO, 2002, 36). More importantly, the Doha Declaration conferred on member countries the right to grant compulsory licenses as well as the freedom to determine the grounds upon which such licenses are to be granted. Taking the stance of the research-based pharmaceutical industry into account, the Doha Declaration has been considered a triumph for consumers and producers of pharmaceutical products in developing countries.

During the same meeting held by the TRIPS Council on June 27, 2002, the Council also approved the waiver that will exempt least-developed countries from the commitment to provide exclusive marketing rights for products whose patent application dates after January 1995 during this period of transition. This waiver is to be submitted to the WTO General Council for approval on July 8, 2002. Both decisions have come to ensure that

‘intellectual property protection supports and does not obstruct poorer countries’ need to tackle serious public health problems” (WTO, 2002).

This decision of the Council for TRIPS conforms to the pre-TRIPS literature on the assumed benefits to developing countries from enforcing higher standards of IPRs. Deardorff (1990) has argued that the extension of intellectual property rights to the entire world is inefficient, in the sense that it will result in disproportionate costs to be borne by poor countries. The poorest of developing countries were the proposed candidates to be left out of a system of otherwise global IPRs (Deardorff, 1990:500-1).

7.3 Egypt’s IPRs Regime

Patent Law 132 of 1949 emerged as one of the most consistent denominators which characterized Egypt's patent regimes during the 1960s, 1970s, 1980s and 1990s.

According to Law 132 of 1949, patents were granted for every new invention susceptible to industrial exploitation, whether related to industrial products, to new industrial processes or to new application of known industrial methods or ways. The exclusion from the framework of patents, however, covered chemical inventions including foodstuff and pharmaceutical products. It was during this early period characterized by shortages in supply as well as very limited innovative capacity in the domain of pharmaceuticals that the logic underlying the exclusion of pharmaceuticals from patentability can be understood.

After several decades of being virtually absent, the developmental role of patents was at the heart of the debate surrounding the future of the pharmaceutical industry following Egypt becoming a signatory of the TRIPS Agreement in 1995. The debate engaged the key stakeholders involved, from industrialists to policy makers and from media specialist to consumer protection agencies.

In 2002, the new TRIPS consistent Law 82 on the 'Protection of Intellectual Property Rights' was enacted, replacing law 132/1949. While the new law stipulated that the period of pharmaceutical product patent protection is twenty years, in an environment where the

science and technology base is weak, and where the innovative capabilities of local pharmaceutical companies remains largely absent, the new patent regime presented a new challenge of a continuous nature to generic companies operating in Egypt.

Having made use of the longest transition period allowed for developing countries under the framework of the TRIPS Agreement, Egypt did not enforce TRIPS consistent pharmaceutical product patent protection except in January 2005. Egypt was, however, obliged to meet all other TRIPS transitional requirements by January 1, 2000. Under the provisions of the TRIPS Agreement, the Government of Egypt was obliged to provide full protection of process patents as stipulated by Article 28, formal protection of confidential data (Article 39.3) and the patent mailbox and EMR (Article 70.8 and 70.9).

On the transitional obligations front, Article 43 of the Agreement stipulated that as of January 1st, 1995, Egypt's Patent Office is to receive pharmaceutical patent applications, and shall maintain such applications, pending their examination as of 1st January 2005. This is what has been commonly known as the 'mailbox' provision.

Accordingly, the Egyptian Government activated the mailbox provision, and Prime Ministerial Decree No. 547 of 2000 was issued to ensure EMRs. Prime Ministerial Decree 2211 was also issued in November 2000 to safeguard data protection.

In Egypt, while data protection for a period of five years has been enforced in accordance to Prime Ministerial Decree 2211 and has been integrated in Law 82/2002, the interpretation is significantly different compared to other countries such as Jordan for example.[27] In Egypt, generic companies are allowed to run their own tests and submit their own data to the regulatory authorities for marketing approval for drugs subject to data protection. From the perspective of the Egyptian government this interpretation is not in conflict with Article 39.3 of the TRIPS Agreement, since the regulatory authorities have not been engaged in the disclosure of protected data. Prior to the issuance of Prime

[27] In October 2000, Jordan and the USA singed a free trade agreement (FTA), with various TRIPS-plus stipulations including the interpretation of data protection.

Ministerial Decree 2211, generic companies were only obliged to refer to the information submitted by innovator drugs to approve their own application.

After having covered the policy and regulatory settings, the following section presents a brief review concerning the operation of generic pharmaceutical companies under the framework of the pre-January 2005 IPRs regime.

7.3.1 Operation of generic pharmaceutical companies under the framework of the pre-January 2005 IPRs regime

Up to December 2005, the exclusion of pharmaceutical products from patentability in Egypt meant that local companies were able -if they decide to do so- to immediately manufacture products, which were still under patent protection in major world pharmaceutical markets without negotiating with the patent holder or paying the due royalty fees involved in case the product was to be manufactured under license. The pre-January 2005 IPRs regime, has thus allowed local generics companies to compete with patent holders over local market shares as well as shares in export markets. These market shares would have otherwise been exclusive to the patent holder. However, for local generics companies in Egypt to be able to copy in-patent products, these products had to be already present on the market and registered with the Ministry of Health.

For a local company to start manufacturing a generic version of a patent-protected product already present on the local market by virtue of being imported or manufactured by one of the subsidiaries of foreign research-based companies operating in Egypt, the only requisite was the provision of the certificate of bioequivalence indicating that the generic version submitted for registration has comparable therapeutic effects as the originator product. The certificate which is submitted to the regulatory authorities cites the name of the originator company, the brand name of the product, the batch number, the registration and expiration dates. This information is filed by the Ministry of Health (Interview, Hossam Aboulenein, Business Development Manager, SEDICO, May 2004). The regulatory authorities in Egypt have often been blamed by the research-based industry of facilitating the process of consulting and referring to the files submitted by originator products in order to facilitate

the process for generics companies to register their products. The newly emerging private sector of the 1980s and 1990s clearly had a wide palate of products to copy, without breaking any laws in Egypt. This fact was an important source of competitive pressure levied on subsidiaries of foreign companies operating in Egypt, who were more often than not reluctant to bring their latest products to the Egyptian market out of fear of infringing activities (Interview, Dr. Mohamed Roushdy, Regional Director, Pfizer Middle East, April 2004).

The ability to infringe pharmaceutical patents in Egypt, without actually breaking any law has had important cost related implications. As a result of bypassing both the payment of royalty fees as well as sourcing raw material inputs from low-cost countries, generic companies benefited from a relatively lower cost structure as well as higher profitability margins than would have otherwise occurred with production under license.

The public business sector

In addition to being the early players on the Egyptian pharmaceutical production scene, public business pharmaceutical companies have also upheld the practice of respecting the rights of patent owners, despite the fact that pharmaceutical process rather than patents have been respected in the domain of pharmaceutical production. Respecting the rights of patent owners allowed public companies to gain the know-how needed to be able to manufacture the product once it was off-patent. Manufacturing a product under license also meant that savings reached 30-70 percent of import value (Sallam, 1981). Refraining from infringing patents, which were still upheld in major world pharmaceutical markets, was a fact acknowledged by foreign companies operating in Egypt. The Managing Director of Pfizer Egypt argued that the threat of infringing activity has emanated mainly from the private, with the public business described as 'respectable' in terms of acknowledging the rights of patent holders (Interview, Dr. Mohamed Roushdy, Regional Director, Pfizer Middle East, April 2004).

The private sector

Relative to the public business sector, Egypt's private sector was more active in taking advantage of excluding pharmaceutical products from patentability. The Egyptian market provides a group of interesting cases documenting the ease by which the local generic companies began to expand their presence on the local market during the 1980s and beyond on the basis of exploiting the country's patent regime to their favour.

Pharco, which is one of the local private sector companies which began operation in 1982, initially had strong relations with foreign licensors, yet it was also successful in exploiting this relationship to expand its market shares to its own advantage given the absence of product patent protection for pharmaceuticals in Egypt. Pharco exploited its relationship with licensors to manufacture a generic version of products manufactured under license once the agreement ends. Bristol Myers was the licensor of one of Pharco's best-selling products, which was the antibiotic 'Duricef'. When the merger between Bristol Myers and Squibb took place, the license was ended because the product competed with Squib's best-selling product 'Velocef'. Pharco took advantage of the know-how gained during the period it held the license for Duricef, and launched its own generic version in 1991, giving its own brand name of 'Curisefe'. BMS's 500mg vial sells for LE 6.3, while Pharco's Curisefe sells for LE 6 (CIB, 1998). The price differential between the originator brand and the competing generic version was surprisingly very low.

However, with infringing activity by the local segment of the Egyptian pharmaceutical industry -private and public- estimated to range between 3-4 percent of the total market (Al-Ahram Al-Iktesadi, 16.01.2004; Al-Ahram Daily, 13.12.99; Subramanian and Abd-El-Latif, 1996), it is safe to argue that local manufacturers of generic products have not *'fully'* exploited lax IPRs standards in Egypt to expand their product portfolios and accordingly their market shares.

This relatively small share has also meant that concern regarding the impact of the TRIPS Agreement on the local segment of the industry has been blown out of scale. In spite of evidence regarding the small share accounted for by infringing products on the Egyptian

market, during the build up to January 2005, pharmaceutical manufacturers in Egypt lobbied extensively to convince policy makers of the potentially negative impact of the Agreement on the survival of this industry. The strategy was to downplay the supply side profitability implications of the TRIPS Agreement, as well as the associated transitional arrangements, having focused instead on the demand side price impact. While this tactic proved to have limited success in terms of altering government commitment to the TRIPS Agreement, it proved successful in terms of the interpreting some clauses of the new patent law to the favour of the local industry. A case in point is the interpretation of data protection to the advantage of manufacturers of generics.

Impact of transitional arrangements: EMRs

Having preceded the enforcement of pharmaceutical patent protection, the impact of enforcing EMRs on market dynamics has been felt at an earlier stage on in Egypt. The case of Eli Lilly's brand-name 'Zyprexa' is a case in point. In 2003, the Egyptian judicial system refused a request submitted by Apex -one of the local Egyptian generics companies- to revoke the decision to grant Eli Lilly EMRs for one of its products. In 1998, Eli Lilly was granted EMRs for its brand-name product Zyprexa, with the active ingredient/molecule being 'Olanzapine' (Al-Ahram Weekly, 2003). The verdict was based on Prime Ministerial Decree 547 of 2000, which authorized the Academy of Scientific Research and Technology to grant certificates of EMRs.

Zyprexa, which has some 20 patents wrapped around it, has been approved for marketing by the FDA in September 1996, with Olanzapine categorized as a NME. It was only in 2005, that competing generic products within the Olanzapine molecule began to emerge on the Egyptian market, when Apex launched the first generic version. In 2007, the second competing generic product surfaced. One year following the launch of the competing generic product, Zyprexa lost 36 percent of the Olanzapine market, and by 2008 it lost 57 percent (Table 7-1). The case of Zyprexa demonstrated two key developments concerning Egypt's pharmaceutical market. The first is that the loss to consumers as a result of the absence of generic entry because of EMRs was significant. Generics in the domain of the Olanzapine molecule have been introduced at an average of 30 percent of the price of the

originator brand. The second development concerned the steep loss in the market share of the originator brand upon generic entry, indicating that Egyptian consumers have been quick in terms of shifting demand to lower priced generic products within the domain of Olanzapine.

Table 7-1: Market shares of the originator brand and generic entrants in the domain of Olanzapine (percent)

Product	Manufacture	Launch Year	Pack	2004	2005	2006	2007	2008	Public Price 2009 (LE)
Zyprexa	Eli Lilly	1998	TABS 5 MG 14	73.3	57.5	35.7	26.4	23.8	160
Zyprexa	Eli Lilly	1998	C.TAB 10 MG 7	26.7	42.0	28.2	25.5	19.0	160
Olapex	Multiapex Ph.	2005	FILM C.TABS 10 MG 30	0.0	0.3	24.2	31.1	34.9	180
Olapex	Multiapex Ph.	2005	FILM C.TABS 5 MG 30	0.0	0.2	11.9	13.4	15.6	120
Olazine	Eipico	2007	FILM C.TABS 10 MG 7	0.0	0.0	0.0	3.6	6.6	35

Source: Based on data from IMS Health Egypt, 2009

7.4 Empirical Strategy

The TRIPS Agreement had no impact in terms of increases in prices or shifts in market shares for products which have already been on the market when it came into force in January 1995. As such, the impact of the Agreement has been exclusive to products/molecules whose patent applications were filed after it came into force. Bearing this fact in mind, the method resorted to in order to address the research questions regarding the impact of the TRIPS Agreement on Egypt's pharmaceutical market was fairly straight forward. The impact of enforcing a 20-year period of pharmaceutical product patent protection in Egypt has been manifested in the "*inability*" of domestic generics companies to manufacture new products for which the patent application on the active ingredients/molecules has been filed after January 1995. The impact of the TRIPS Agreement can, therefore, be quantified by the market value captured by these new products/molecule.

Accordingly, as a first step, and based on data obtained from IMS Egypt, the identification of new molecules placed on the Egyptian pharmaceutical market by research-based companies, which have not been facing generic competition was undertaken. This scan was

undertaken in conjunction with respective market shares for these new molecules/products, and the associated cost to consumers.

According to IMS data, the Egyptian market is segmented into some 600 therapeutic classes, with detailed product-level information concerning therapeutic classes, propriety name, manufacturer, launch year, pack size and strength and molecule. Since it was not feasible to investigate demand and market dynamics in all of the 600 classes, a sample of the country's 42 largest therapeutic classes in terms of market value has been selected to support the analysis (Annex Table 12). Together the 42 therapeutic classes account for more than 50 percent of Egypt's LE 12.6 billion (USD 2.3 billion) retail pharmaceutical market. The 42 therapeutic classes also cover essential products, meaning that all classes which were either related to life-style or are of an over-the-counter/non-essential nature have been excluded. The share of the 42 therapeutic classes subject to analysis will, therefore, significantly increase if the market share is exclusively related to essential drugs.

All new molecule placed on the market by research-based pharmaceutical companies were scanned for the presence/absence of competing generic products within each molecule. In conjunction with launch dates, and taking evidence regarding the absence of generic competition within any given new molecule a step further, a search for the status of the concerned molecule/brand-name was undertaken in the Orange Book of the USA FDA. This search provided information regarding the approval date of the brand-name/molecule on the US market, as well as patent and exclusivity data.[28] For each candidate molecule, patent data was checked against information provided by the United States Patent Office for details regarding patent filing dates. A parallel search was also conducted at the Centre for Drug Evaluation and Research of the USA FDA, to identify the chemical type of the active ingredient/molecule. All products falling in the domain of candidate molecules were assessed in terms of trends regarding market shares, as well as in terms of the overall cost to consumers during the period 2004-2008 for which data was available.

[28] The FDA has been selected as the key source of information regarding new pharmaceutical molecules because of the sheer size of the US market as well as the fact that the US is the home country of some of the largest of the research-based pharmaceutical companies.

7.5 Quantifying the Impact of the Trips Agreement on Egypt's Pharmaceutical Market

The impact of enforcing TRIPS consistent pharmaceutical patent protection in Egypt has been manifested in the market absence of domestic as well as imported generic- products whose active pharmaceutical ingredients are protected by patents. While these patents are mainly foreign, applications have also been made in Egypt.

Two scenarios regarding impact can be expected. Firstly, if new patent protected products do not capture market shares of significance in the concerned therapeutic classes, with consumers favouring to retain consumption of already existing bioequivalent products within the same therapeutic class, then the static impact will not be felt. Secondly, if consumers/prescribing physicians shift their demand/prescription preferences to newly introduced products, whereby significant changes in the market shares of new and old products within the concerned class become evident, then the static impact in terms of adverse welfare effects occurs through relatively higher prices, as well as immediate shifts in market shares. The pertinent question is thus related to the nature of shifts in the market shares of new versus old substitutes within the same therapeutic class, as well as the relative prices of these products and the associated cost to consumers.

7.5.1 New patent protected products on Egypt's pharmaceutical market

A first step was to identify new products which have not been facing generic competition on Egypt's pharmaceutical market. Results indicate that in 14 of the 42 study therapeutic classes, there was evidence regarding launches of new molecule by research-based pharmaceutical companies on the Egyptian market, with no evident generic competition. Together the 14 therapeutic classes account for 2 percent of the Egyptian pharmaceutical market by value, as well as 14 percent of the sample therapeutic classes.

Table 7-2 presents the summary results concerning the assessment of the impact of the TRIPS Agreement on Egypt's pharmaceutical market. Within the 14 therapeutic classes, which have been impacted on by the TRIPS Agreement, a total of 24 molecules have not been facing generic competition against brand-name products falling within their domain.

Between 2004 and 2008, Egyptian consumers paid a total LE 605 million for products falling within the domain of new molecules, which faced no generic competition.

Examining the patentability status of the 24 molecules indicated that 5 molecules did not qualify as 'new'. The patent filing dates for these molecules were dated before the TRIPS Agreement came into force. These molecules are Insulin Lispro in the domain of human insulin, Benazepril and Fosinopril in the domain of ace inhibitors plain, Perindopril in the domain of Ace Inhibitors and Fluvastatin in the domain of Statins. The absence of generic competition within the domain of the 5 molecules, however, indicated that other barriers have prevented generic products from emerging on the market. Among the barriers encountered by local generic companies are those related to the difficulty in procuring the active ingredient. A case in point was related to the failure to import the active ingredient of human insulin, owing to the monopoly position enjoyed by one of the largest research-based companies in this domain (Interview, Hossam Aboulenein, Business Development Manager, SEDICO, April 2004). For the 5 molecules, consumers paid a total LE 126 million for products falling in their domain (Table 7-3).

The results of the analysis presented in chapter 5 indicated that for the sample of molecules covered, average generic-to-originator prices in Egypt stood as high as 73 percent. On this basis, had generics been present on the market, and on the assumption that consumers will opt for the generic version, then the real cost to consumers is the difference between what they incurred in cost towards purchasing patent protected drugs and what they would have otherwise paid for generics. This difference stood at a total of LE 129 million between 2004 and 2008.

Table 7-2: New molecules facing no generic competition in Egypt, 2004-08

	Class/ Propriety name	Molecule	Manufacturer	Launch in Egypt	Marketing approval by the FDA	First patent to expire		Last patent to expire		Market share		Sales Value LE
						Filling date	Expiry date	Filling date	Expiry date	2004	2008	04-08
1	Nexium	Esomeprazole	AstraZeneca	2006	Feb. 2001	Sept.94	2014	Feb. 2000	Nov. 2019	4.9	8.2	39,277
2	Novomix 30	Insulin Aspart	Novo Nordisk	2004	Jun-00	Sep.93	Sep, 2013	Jun-97	2017	0.58	5.5	17,048
3	Plavix	Clopidogrel	Sanofi-Synthelabo	2001	Nov. 1997	Feb. 88	Nov. 2011	Jun-02	2019	99	64	187,232
4	Atacand Plus	Candesartan Cilexetil	AstraZeneca	2006	4-Jun-98	Nov. 06	18-Apr-11	Nov. 18, 1992	Jul 9, 2013.	1.9	7.4	11,101
5	Micardis Plus	Telmisartan	Boehringer	2005	Nov. 17, 2000	Jun-95	Jan. 7, 2014	Jan. 10, 2000	Jan. 10, 2020	4	5	10,271
6	Lipostat	Pravastatin.	BMS Egypt	1994	Oct. 31, 1991	Mar. 31, 88	9-Jul-08	19-Apr-95	22-Apr-14	9.7	2.3	24,308
7	Tazocin****	Piperacillin	Wyeth	2000	Oct. 22, 1993	3-Apr	14-Apr-23			0.47	0.32	1,454
8	Ketek	Telithromycin	Aventis	2002	1-Apr-04	Apr-95	1-Apr-18	Sept. 24, 2001	Sept. 24, 2015	4.8	0	5,307
9	Hepsera	Adefovir Dipivoxil	GSK	2008	20-Sep-02	Oct. 94	Sept. 2, 2014	Sept. 10, 2001	23-Jul-18		1.2	1,109
10	Reiferon Retard	Interferon ALFA	Rhein	2007	Oct. 10, 1989	n.a.	n.a.	n.a.	n.a.	0.26	17.9	18,041
11	Pegasys	Peginterferon Alfa-2A	Roche	2006	Oct. 16, 2002	n.a.	n.a.	n.a.	n.a.	18.3	41.5	65,110
12	Pegintron	Peginterferon Alfa-2A	Schering Plough	2006	Jan. 19, 2001	n.a.	n.a.	n.a.	n.a.	15.9	8.3	23,110
13	Trileptal	Oxcarbazepine	Novartis Egypt	1994	25-May-01	May 03.	Feb. 12, 2018	n.a.	n.a.	3.8	6	35,440
14	Zeldox	Ziprasidone	Pfizer Egypt	2004	Feb. 5, 2001	Jan. 88.	2-Mar-12	27-May-99	27-May-19	7.8	1.6	8,366
15	Serdolect	Sertindole	Lundbeck	2008	n.a.	n.a.	n.a.	n.a.	n.a.		0.9	716
16	Seroquel	Quetiapine	AstraZeneca	2004	Sept. 26, 1997	Mar-87	26-Sep-11	28-May-97	28-Nov-17	7	9	21,811
17	Vigamox	Moxifloxacin	Alcon	2007	15-Apr-03	Jun-89	Dec. 8, 2011	22-Jul-02	29-Sep-19	5.4	6	9,585
	Cost to consumers											479,286

Table 7-3: Molecules facing no generic competition, with patent filing dates falling before 1995

	Class/ Propriety name	Molecule	Manufacturer	Launch in Egypt	Marketing approval by the FDA	First patent to expire		Last patent to expire		Market share		Sales Value LE
						Filling date	Expiry date	Filling date	Expiry date	2004(1)	2008	04-08
1	Humalog Mix 25	Insulin Lispro	Eli Lilly	2005	June 1996	Jun. 94	2014	May 1993	2013	0.06	3.10	6,640
2	Cibacen	Benazepril	Novartis Egypt	1993	March 1995	Mar. 92	Dec. 2017	n.a.	n.a.	0.46	0.37	1,041
3	Monopril	Fosinopril	BMS Egypt	1995	May16, 1991	June 90	2009	n.a.	n.a.	4.60	3.20	13,256
4	Cibadrex	Benazepril	Novartis Egypt	1995	March 1995	March 92	Dec. 2017	n.a.	n.a.	0.10	1.27	2,177
5	Monozide	Fosinopril	BMS	1999	May16, 1991	June 90	2009	n.a.	n.a.	8.70	5.08	23,638
6	Preterax	Perindopril	Servier Egypt.	2003	Dec.30, 1993	Dec. 83	Nov. 2009	n.a.	n.a.	5.33	5.98	20,258
7	Lescol	Fluvastatin.	Novartis Egypt	1994	Dec.31, 1993	Nov. 93	Oct.11, 2011	Dec. 22, 1992	Jun 12, 2012	14.50	9.50	58,490
	Cost to consumers											125,499

2004 was selected as the base year, as EMR have been enforced prior to 2005 and hence it was also important to capture its' impact
Sources: IMS Egypt , 2009; USA Patent Office, 2011; Orange Book, 2011

7.5.2 To what extent have Egyptian consumers been willing to trade-off lower prices of older drugs, for more innovative new products?

In order to assess the extent to which Egyptian consumers have been willing to trade-off lower prices of older drugs for more innovative new products, results concerning shifts in market shares between old and new molecules have revealed important findings regarding consumer preference for new generation molecules. In 15 out of the 24 molecules, consumer demand has been gradually shifting in favour of new products introduced (Table 7-4). This shift has been occurring despite the fact that relative prices of new products are much higher than older generation molecules already present within the same class. The shaded rows in Table 7-4 highlight new molecules in which only originator products are present.

Table 7-4: Shifts in consumer demand towards new generation molecules placed on the Egyptian market between 2004-2008

Class and Molecule	Number of products	Number of generics	Launch year	Sales as a % of total class					Mean price* in molecule
				2004	2005	2006	2007	2008	
1- A02B2 ACID PUMP INHIBITORS SALES (LE '000)				76,882	115,403	151,168	191,371	234,445	
OMEPRAZOLE	19	18	1993	68.4	60.1	50.3	47.8	44.9	44
LANSOPRAZOLE	8	7	1994	9.9	8.4	7.0	6.9	5.3	39
PANTOPRAZOLE	9	8	1997	10.6	20.6	26.7	28.2	30.7	33
DOXYCYCLINE	1	1	1998						51
TINIDAZOLE	4	4	1998	4.2	4.0	4.5	3.8	3.8	70
RABEPRAZOLE	5	2	2001	11.1	10.8	11.1	10.5	10.9	19
CLARITHROMYCIN	3	3	2003	3.8	3.8	4.3	3.7	3.8	76
NEW - ESOMEPRAZOLE	**1**	**0**	**2006**	**-**	**-**	**4.9**	**6.6**	**8.2**	**132**
2-A10C3 H INSUL+ANA INT+FAST ACT SALES (LE '000)				45,830.2	71,699.7	89,428.3	99,662.0	101,632.4	
INSULIN HUMAN ISOPHANE	3	1	1991	96.1	95.4	90.7	82.5	83.6	40
INSULIN HUMAN BASE	2	1	2002	3.0	1.2	3.6	10.4	7.8	16
NEW- INSULIN ASPART PROTAMINE CRYSTALLINE	**1**	**0**	**2004**	**0.9**	**3.4**	**4.3**	**4.8**	**5.5**	**340**
NEW- INSULIN LISPRO PROTAMINE	**1**	**0**	**2005**	**-**	**0.1**	**1.4**	**2.2**	**3.1**	**330**
3-B01C2 ADP RECEP ANTAG PLAT INH SALES (LE '000)				24,707.4	36,253.3	51,091.9	65,062.1	78,017.2	
TICLOPIDINE	2	1	1993	0.3	0.1	0.0	0.0	-	49
CLOPIDOGREL	8	5	2001	99.7	99.9	100.0	100.0	100.0	139
4-C09A0 ACE INHIBITORS PLAIN SALES (LE '000)				61,554.2	70,882.3	80,213.3	90,252.1	91,213.3	
CAPTOPRIL	6	5	1983	27.2	33.0	30.5	32.9	31.8	9
NEW- BENAZEPRIL	**1**	**0**	**1993**	**0.5**	**0.1**	**-**	**0.4**	**0.4**	**25**
LISINOPRIL	5	4	1994	17.3	14.5	15.4	15.1	12.4	13
PERINDOPRIL	2	1	1994	19.0	17.3	19.5	17.6	17.5	61
RAMIPRIL	4	3	1994	25.9	23.7	24.5	24.8	26.4	23
ENALAPRIL	5	4	1995	4.9	6.0	4.8	4.2	6.6	11
NEW- FOSINOPRIL	**1**	**0**	**1995**	**4.5**	**4.0**	**3.4**	**3.0**	**2.8**	**20**
NEW- MOEXIPRIL	**1**	**0**	**2004**	**0.7**	**1.4**	**1.9**	**2.0**	**2.1**	**27**

Cont. Table 7-4

Class and Molecule	Number of products	Number of generics	Launch year	Sales as a % of total class					Mean price* in molecule
				2004	2005	2006	2007	2008	
5-C09B1 ACE INH COMB+A-HYP/DIURET SALES (LE '000)				44,125.2	64,750.7	80,556.7	96,621.8	98,566.7	
CAPTOPRIL	5	4	1990	40.6	48.8	46.5	48.8	43.9	18
NEW- BENAZEPRIL	**1**	**0**	**1995**	**0.1**	**0.0**	**-**	**0.9**	**1.3**	**35**
ENALAPRIL	4	3	1995	8.2	10.0	10.7	11.7	18.7	16
LISINOPRIL	3	2	1997	21.1	17.0	19.8	17.4	13.8	21
NEW- RAMIPRIL	**1**	**0**	**1997**	**16.0**	**12.1**	**11.6**	**11.0**	**11.4**	**19**
NEW- FOSINOPRIL	**1**	**0**	**1999**	**8.7**	**7.1**	**6.2**	**5.4**	**5.1**	**21**
INDAPAMIDE	3	1	1999	8.6	7.8	7.6	7.1	8.4	58
NEW- PERINDOPRIL	**2**	**0**	**2003**	**5.3**	**4.9**	**5.2**	**4.9**	**6.0**	**71**
6-C09D1 AT2 ANTG COMB C2 &/O DIU SALES (LE '000)				22,114.9	31,092.4	46,670.6	63,495.8	81,447.9	
LOSARTAN	11	9	1998	37.0	32.8	31.4	30.3	27.0	26
VALSARTAN	3	1	1998	63.0	63.1	57.5	49.4	43.6	45
TELMISARTAN	1	1	2005	-	4.0	4.1	4.7	5.1	121
NEW-CANDESARTAN CILEXETIL	**1**	**0**	**2006**	**-**	**-**	**1.9**	**6.5**	**7.4**	**90**
IRBESARTAN	2	1	2006	-	-	5.1	9.2	16.9	52
7-J01F0 MACROLIDES & SIMILAR TYPE SALES (LE '000)				94,033.9	109,243.0	128,336.7	147,974.0	169,640.5	
ERYTHROMYCIN	5	4	1984	8.8	9.0	6.1	5.3	4.5	7
SPIRAMYCIN	9	7	1994	20.1	18.4	19.0	19.4	16.2	15
CLINDAMYCIN	5	3	1987	10.2	11.9	12.3	12.3	12.7	17
NEW- LINCOMYCIN	**1**	**0**	**1987**	**1.4**	**2.3**	**3.1**	**2.1**	**2.3**	**15**
ROXITHROMYCIN	3	2	1993	0.4	0.2	0.4	0.4	0.5	20
AZITHROMYCIN	11	10	1995	41.4	46.3	48.1	49.7	53.2	27
CLARITHROMYCIN	4	2	1999	12.1	10.7	10.7	10.8	10.7	40
MIDECAMYCIN	1	1	2001	0.9	0.6	0.2	0.0	0.0	26
NEW- TELITHROMYCIN	**1**	**0**	**2002**	**4.8**	**0.6**	**0.1**	**0.0**	**-**	**126**
METRONIDAZOLE	1	1	2003	0.1	0.0	0.5	1.6	1.7	13

Cont. Table 7-4

Class and Molecule	Number of products	Number of generics	Launch year	Sales as a % of total class					Mean price* in molecule
				2004	2005	2006	2007	2008	
8-J05B1 VIRAL HEPATITIS PRODUCTS SALES (LE '000)				11,248.6	15,429.8	29,018.8	57,665.7	95,663.3	
RIBAVIRIN	5	5	1997	54.5	60.2	38.0	33.1	31.8	63
LAMIVUDINE	2	1	2002	45.5	21.5	13.0	10.6	7.7	180
NEW- INTERFERON ALFA	**1**	**0**	**2006**	**-**	**-**	**0.3**	**1.5**	**17.9**	**213**
NEW- PEGINTERFERON ALFA-2B	**2**	**0**	**2006**	**-**	**18.3**	**48.7**	**54.9**	**41.4**	**1,253**
NEW- ADEFOVIR DIPIVOXIL	**1**	**0**	**2008**	**-**	**-**	**-**	**-**	**1.2**	**520**
9-N03A0 ANTI-EPILEPTICS SALES (LE '000)				79,889.8	105,449.6	122,939.6	166,779.8	195,646.8	
CLONAZEPAM	9	8	1978	6.2	11.2	9.7	8.0	6.9	8
CARBAMAZEPINE	8	7	1985	37.4	33.2	29.4	26.8	25.7	25
NEW- OXCARBAZEPINE	**1**	**0**	**1994**	**3.8**	**3.7**	**5.5**	**5.9**	**6.1**	**78**
VALPROIC ACID	5	3	1994	27.1	24.0	23.6	19.7	17.1	20
PHENYTOIN	5	3	1995	5.3	4.8	3.9	3.2	2.4	11
GABAPENTIN	4	3	2002	10.7	12.8	14.5	14.1	15.1	46
LAMOTRIGINE	3	2	2002	7.0	6.9	8.8	7.8	8.4	40
TOPIRAMATE	3	2	2002	2.3	3.3	4.3	4.0	4.1	108
LEVETIRACETAM	3	3	2006	-	-	0.3	1.5	2.8	261
PREGABALIN	2	1	2007	-	-	-	9.0	11.3	119
10-N05A1 ATYPICAL ANTIPSYCHOTICS SALES (LE '000)				30,488.9	44,055.9	56,569.0	65,769.5	83,582.5	
CLOZAPINE	5	4	1982	33.7	27.2	20.7	20.1	18.9	49
RISPERIDONE	9	8	1997	47.8	43.7	41.2	40.2	38.2	87
OLANZAPINE	3	2	1998	10.3	15.5	17.9	18.0	18.9	131
NEW- QUETIAPINE	**1**	**0**	**2004**	**0.4**	**6.9**	**8.6**	**9.0**	**9.5**	**310**
NEW- ZIPRASIDONE	**1**	**0**	**2004**	**7.8**	**4.3**	**2.2**	**2.2**	**1.6**	**120**
ARIPIPRAZOLE	3	1	2005	-	2.4	9.4	10.5	12.0	115
NEW- SERTINDOLE	**1**	**0**	**2008**	**-**	**-**	**-**	**-**	**0.9**	**304**

Cont. Table 7-4

Class and Molecule	Number of products	Number of generics	Launch year	Sales as a % of total class					Mean price* in molecule
				2004	2005	2006	2007	2008	
11-S01A0 ANTI-INFECTIVES-EYE SALES (LE '000)				50,861.9	58,290.5	63,543.9	73,903.7	92,226.8	
GRAMICIDIN	2	1	1978	0.8	0.7	0.8	1.0	0.7	5
CHLORAMPHENICOL	7	7	1980	14.1	12.2	10.8	9.1	6.9	2
NEOMYCIN	4	3	1980	0.9	1.3	1.6	2.1	2.0	4
NEW- HYPROMELLOSE	**1**	**0**	**1982**	**0.2**	**0.1**	**0.1**	**0.1**	**0.1**	**5**
BACITRACIN	2	2	1983	0.0	0.0	0.0	-	-	7
GENTAMICIN	5	4	1983	1.7	1.1	0.8	0.7	0.4	3
SULFACETAMIDE	3	2	1984	1.3	0.7	0.6	0.5	0.3	1
TOBRAMYCIN	6	4	1985	12.2	12.5	14.1	16.0	15.2	8
FUSIDIC ACID	2	1	1993	5.3	7.1	6.6	8.2	7.4	14
OFLOXACIN	7	6	1996	12.5	11.8	11.3	11.2	9.9	8
CIPROFLOXACIN	4	3	1999	9.6	8.6	9.7	8.6	6.4	9
OXYTETRACYCLINE	3	2	1999	32.4	35.5	33.1	26.0	30.4	3
NEW- TRIMETHOPRIM	**1**	**0**	**1999**	**0.4**	**0.2**	**-**	**-**	**-**	**14**
NORFLOXACIN	1	1	2000	0.5	0.5	0.4	0.3	0.3	2
LOMEFLOXACIN	2	2	2003	8.0	6.8	6.6	7.1	5.9	12
GATIFLOXACIN	4	4	2005	-	0.9	3.8	3.6	7.4	20
NEW- MOXIFLOXACIN	**1**	**0**	**2007**	**-**	**-**	**-**	**5.4**	**6.1**	**45**

*Per pack
Source: IMS, 2009

7.5.3 Shifts in the market shares of local versus research-based companies

Within the context of evaluating the impact of the TRIPS Agreement on Egypt's pharmaceutical market, it was important to also assess the extent to which the post-2005 environment has been associated with a parallel decrease in the market shares of local versus foreign players in the domain of the therapeutic classes which saw the introduction of new patent protected products.

Market data indicated that between 2004 and 2008, the local private sector has maintained the position of the dominant player in 6 out of the 14-candidate therapeutic classes which saw the introduction of patent-protected products (Table 7-5). In 5 of these classes, in addition to maintaining the largest market share, the local private sector has actually been consolidating its position of dominance by virtue of increasing market shares. While still accounting for the dominant share, in only one of the 6 classes, was there evidence that the private sector has been losing market shares, namely in the acid pump inhibitors class. The acid pump inhibitors class is the largest in terms of market value among the 14 classes.

Local generics companies have been consolidating their position in 3 classes in which they maintain a minority share. These are the anti-epileptics, the Human insulin and in the AT2 antagonist combination C2 &/O DIU class. The sharpest increase in market shares accounted for by the private sector occurred in the AT2 antagonist combination C2 &/O DIU class, with an increase in market shares from 0.5 percent in 2004 to 16.7 percent in 2008.

The local private sector has, nonetheless, been losing market shares in 5 classes. The sharpest decline in market shares has been in the domain of the Ace inhibitors INH COMB+A-HYP/DIURET class, whereby its market share dropped from 25.3 percent in 2004 to 10.7 percent in 2008.

Unlike the local private sector, which has exhibited relatively healthy trends regarding market shares, indicating resilience in the face of competition from the imported sector as well as from subsidiaries of research-based companies manufacturing under license in

Egypt, the situation of the public business sector sends an important message regarding agility. Historically, the public business sector has been the provider of the lowest priced pharmaceutical products in Egypt. The gradual loss in market shares indicates that this sector has not been keeping up with the private sector in terms of new product launches, and has largely retained a product portfolio which is dominated by older generation drugs. While marketing resources available to the public business sector have also been significantly lower than that of the private sector, this situation reflects the overall financial well-being of this sector, which for years has been captivated to fulfil the social objective of providing low-priced pharmaceuticals to the majority of Egyptian consumers (indirectly subsidised prices by virtue of the government controlling upward price movements).

Subsidiaries of research-based pharmaceutical companies are the dominant players in only three out of the 14-study therapeutic classes. These are the anti-epileptics, the ace inhibitors INH COMB+A-HYP/DIURET and the AT2 antagonist COMB C2 &/O DIU classes. While maintaining a position of dominance in the three classes, the multinational sector has been gradually loosing market shares in all three.

In five of the 14 classes, there has been evident deterioration in the market shares of subsidiaries of research-based pharmaceutical companies, the sharpest of which has been in the broad spectrum penicillin (8.7 percent), in the statins class (16.3 percent) and in the viral hepatitis products (39.1 percent). In only one therapeutic class has the multinational sector been consolidating its share, namely in the macrolides & similar type class, from a minority share of 17.7 percent in 2004, to 20.2 percent in 2008. Otherwise, market shares have remained largely unchanged.

The important observation regarding market shares concerns the imported segment, which has been the dominant player in the four therapeutic classes of Human insulin +ANA INT+FAST ACT, Anti-Infectives-Eye, Atypical Antipsychotics and ADP RECEP ANTAG PLAT INH. In two of the classes in which imported products have been the dominant market players, has there been evidence of market share consolidation. In 6 of the classes in which imported products have maintained a minority share, there was evidence of

consolidation in market position. The sharpest increases in market shares has been evident in the ACE INH COMB+A-HYP/DIURET class of 18 percent between 2004 and 2008, and VIRAL HEPATITIS PRODUCTS of 39 percent during the same period.

In summary, trends regarding market shares mirror important observations. The public business has been losing share on the Egyptian market, and imported products have been rapidly consolidating its position on the market. In fact the most important observation is that contrary to the concerns of the local private sector, the strengthening of the country's IPRs regime in accordance with the TRIPS Agreement has not run parallel to market shifts which indicate that the foreign sector is crowding out the local private sector. In fact, the private sector has been consolidating its position, both in terms of overall market, with visible increases in market shares, as well as within classes which have seen the introduction of new patent protected products.

Table 7-5: Market shares in molecules which saw the introduction of new patent-protected products

		Percent of Therapeutic Class				
		Y/2004	Y/2005	Y/2006	Y/2007	Y/2008
Acid Pump Inhibitors LE Sales*		**76,882**	**115,404**	**151,168**	**191,371**	**234,445**
Holdipharma	↓	4.4	4.1	3.0	2.7	2.2
Imported	↑	23.0	26.8	27.3	27.4	28.5
Multinational	↓	4.7	2.7	3.4	4.3	4.4
Private	↓	***67.8***	***66.4***	***66.3***	***65.6***	***64.8***
N03A0 ANTI-EPILEPTICS LE Sales		**79,890**	**105,450**	**122,940**	**166,780**	**195,647**
Holdipharma	↓	5.5	5.0	4.5	3.8	3.1
Imported	↓	30.1	26.6	28.2	23.4	25.2
Multinational	↑	***44.3***	***39.9***	***38.9***	***45.0***	***46.2***
Private	↑	20.1	28.4	28.3	27.8	25.5
BROAD SPECT PENICILL INJ LE Sales		**76,192**	**98,455**	**126,173**	**156,252**	**173,068**
Holdipharma	↓	6.9	4.9	4.3	3.9	3.5
Imported	↓	0.5	0.2	0.0	0.2	0.3
Multinational	↓	22.7	16.2	14.7	13.3	14.0
Private	↑	***70.0***	***78.7***	***81.0***	***82.6***	***82.2***
MACROLIDES & SIMILAR TYPE LE Sales		**94,034**	**109,243**	**128,337**	**147,974**	**169,641**
Holdipharma	↓	34.4	32.2	28.4	21.7	21.2
Imported	↓	4.8	0.7	0.3	1.3	3.5
Multinational	↑	17.7	18.0	19.3	23.4	20.2
Private	↑	***43.1***	***49.0***	***52.0***	***53.7***	***55.1***
Hepatic Proct Lipotropics LE Sales		**87,316**	**109,094**	**114,201**	**131,609**	**157,547**
Holdipharma	↓	7.2	8.5	7.4	7.0	5.9
Imported	↑	12.4	11.7	11.0	12.9	12.8
Private	↑	***80.4***	***79.9***	***81.7***	***80.1***	***81.4***
STATINS (HMG-COA RED) LE Sales		**60,777**	**74,415**	**93,765**	**116,632**	**131,268**
Holdipharma	↑	0.3	0.2	0.2	0.2	0.4
Imported	↑	0.0	0.0	0.4	5.5	12.9
Multinational	↓	57.6	57.6	53.1	47.4	41.3
Private	↑	***42.2***	***42.2***	***46.2***	***46.9***	***45.5***
Human INSUL+ANA INT+FAST ACT LE Sales		**45,830**	**71,700**	**89,428**	**99,662**	**101,632**
Holdipharma	↑	0.0	0.0	0.2	4.0	3.7
Imported	↓	***94.3***	***98.7***	***94.5***	***84.9***	***89.3***
Private	↑	5.7	1.3	5.3	11.0	7.0
ACE INH COMB+A-HYP/DIURET LE Sales		**44,125**	**64,751**	**80,557**	**96,622**	**98,567**
Holdipharma	↓	7.2	9.2	10.0	11.1	4.5
Imported	↑	8.7	7.4	6.6	12.2	26.6
Multinational	↑	***58.7***	***62.2***	***59.2***	***61.2***	***58.2***
Private	↓	25.3	21.3	24.2	15.5	10.7
VIRAL HEPATITIS PRODUCTS LE Sales		**11,249**	**15,430**	**29,019**	**57,666**	**95,663**
Holdipharma	↓	15.7	11.4	3.4	1.6	0.3
Imported	↑	0.0	18.3	48.7	54.9	41.4
Multinational	↓	45.5	20.4	10.3	7.9	6.4
Private	↑	***38.8***	***49.9***	***37.7***	***35.6***	***51.8***

Cont.

		Percent of Therapeutic Class				
		Y/2004	Y/2005	Y/2006	Y/2007	Y/2008
Anti-Infectives-Eye LE Sales		**50,862**	**58,291**	**63,544**	**73,904**	**92,227**
Holdipharma	↓	16.4	16.5	13.9	12.2	10.5
Imported	↑	***32.2***	***30.7***	***34.5***	***42.0***	***41.3***
Multinational	↑	29.8	32.5	31.8	25.0	30.0
Private	↓	21.6	20.3	19.8	20.9	18.2
Ace Inhibitors Plain LE Sales		**61,554**	**70,882**	**80,213**	**90,252**	**91,213**
Holdipharma	↓	4.4	5.9	4.9	4.2	1.8
Imported	↑	0.0	0.0	0.0	3.6	14.0
Multinational	↓	***71.4***	***70.7***	***69.4***	***69.9***	***70.3***
Private	↓	24.2	23.4	25.7	22.3	13.9
Atypical Antipsychotics LE Sales		**30,489**	**44,056**	**56,569**	**65,770**	**83,583**
Imported	↑	***31.5***	***38.5***	***42.0***	***41.3***	***59.4***
Multinational	↓	26.8	18.5	11.4	11.5	10.5
Private	↓	41.8	43.0	46.6	47.2	30.1
AT2 ANTG COMB C2 &/O DIU LE Sales		**22,115**	**31,092**	**46,671**	**63,496**	**81,448**
Imported	↑	36.5	32.1	32.9	38.5	38.1
Multinational	↓	***63.0***	***63.1***	***57.5***	***49.4***	***45.2***
Private	↑	0.5	4.7	9.6	12.1	16.7
ADP RECEP ANTAG PLAT INH LE Sales		**24,707**	**36,253**	**51,092**	**65,062**	**78,017**
Imported	↓	***100.0***	***81.5***	***72.8***	***70.5***	***82.8***
Private	↑	0.0	18.5	27.2	29.5	17.2

(LE thousand)

Source: Based on IMS, 2009

7.6 Evaluating Perceptions Regarding the Impact of the Trips Agreement on Companies Operating on Egypt's Pharmaceutical Market

In April, 2004, a survey was conducted to evaluate perceptions regarding the impact of the TRIPS Agreement on the various firms which operated on the Egyptian manufacturing scene. All companies operating in the domain of pharmaceutical production in Egypt have been approached to take part of the survey. A total of 25 out of the 42 companies present on the Egyptian market agreed to participate in the survey (nonprobability 'convenience' sampling was followed), including the public business sector, the private sector, subsidiaries of research-based companies as well as local generics companies with a foreign equity share. Face-to-face meetings have been arranged to conduct the survey, whereby for the firms covered, meetings were held with either the chief operating officer or the business development manager. Comparing responses to actual trends during the post-January 2005 phase indicated that accuracy regarding the scope of impact was rather flawed.

The following section presents the survey results and discusses the perceived outcome of the TRIPS Agreement versus the actual outcome on the ground.

Will your ability to introduce new products change after 2005?

	Public	Private local	Private foreign	Private local with foreign equity partnership
Significantly decline	20.0%	18.2%	0.0%	66.7%
Moderately decline	20.0%	27.3%	0.0%	0.0%
No decline	20.0%	18.2%	33.3%	0.0%
Moderately increase	40.0%	36.4%	0.0%	0.0%
Significantly increase	0.0%	0.0%	66.7%	33.3%
Total number of companies	5	11	6	3

Responding to the question regarding the pace by which companies operating under different ownership structures will introduce new products during the post-January 2005 phase reflected significant differences between the responses of each sector. Public business sector companies, as well as local private companies, indicated moderate likelihood in terms of ability to introduce new products. These responses were based on the assumption that the palate of new products which were to be available for copying will no

longer exist. Introducing new products can only be achieved through the manufacturing of 'pure' generics in its strict interpretation according to the TRIPS Agreement. In contrast, and as expected, 67 percent of the respondents to this question from subsidiaries of research-based companies indicated that their rate of new product introductions to the Egyptian market beyond January 2005 was likely to increase significantly owing to the safety awarded to these new products from infringing activities. The response of the mixed ownership segment of the surveyed companies, in which there is a foreign equity share indicated that there will be significant decline in new product introductions, owing to the preference of the licensors to cater to the market through the arms-length exports.

While it has been true that in the domain of molecules examined in this chapter, which are patent protected, there have been no competing product introductions by the generics industry, the overall increase in the market share of the local private sector reflects another story. With respect to the local private sector, the results of the survey are not consistent with the increase in the overall market shares gained by the private sector between 2004 and 2008. The number of products has been on the rise owing to opportunities which emanate from non-infringing activities. The same flaw in perception held true for subsidiaries of research-based companies, who have lost market shares during the same period.

Give the percentage of your sales which may be negatively affected by opening the 'mail-box' after 2005?

	Public	Private local	Private local with foreign equity
0%	25.0%	9.1%	66.7%
<25%	50.0%	45.5%	33.3%
25% +	25.0%	45.5%	0.0%
Total number of companies	4	11	3

A question concerning the impact of opening the mailbox on the market shares of companies surveyed also indicated inaccurate forecasts. As highlighted earlier, the "mail-box" provision basically deals with situations in which countries that choose to delay the introduction of patent protection for pharmaceutical products will have to provide a mechanism of accepting patent applications for inventions which were patented after the

Agreement came into force in January 1995. These patent applications resided unprocessed in this 'mailbox' until this country introduces a TRIPS consistent patent law for pharmaceuticals. Patents for products which were in the mailbox are then granted as if they have been in effect since the Agreement came into force. The patent is therefore enforced for the remaining duration of what is left of the standard 20-year period of patent protection.

Of the 23 companies responding to this question, the response indicated that the bulk of their product portfolios will in fact be jeopardized by the opening of the mail-box in January 2005. The local public as well as private companies indicated that more than 75 percent of their product portfolios will be exposed to market exit or production under proper licensing agreements with the patent-owner once the mail-box is opened. In contrast to these assessment, non-of the products registered on the Egyptian market before the opening of the mail-box in January 2005, have actually exited the market.

Do you anticipate a decline in market share following the enforcement of 20 years of product patent protection after 2005?

	Public	Private local	Private foreign	Private local with foreign equity share
Yes	80.0%	36.4%	.0%	66.7%
No	20.0%	63.6%	100.0%	33.3%
Total number of companies	5	11	6	3

One of the questions for which the response was mixed in terms of accuracy, as indicated by real market shifts after January 2005, was that pertaining to the extent to which the surveyed companies anticipated market shifts of significance in the aftermath of enforcing higher standards of IPRs in Egypt.

Some 80 percent of pubic business companies correctly anticipated a decline in market shares, while the majority of private and foreign companies anticipated an increase in market shares (63 percent and 100 percent respectively). It is important to note that there should be no intrinsic differences in loss of market shares in the aftermath of Janaury-2005

between public as well as private sector companies. In fact, from interviewing company executives, it was repeatedly indicated that public sector companies have been less active in infringing patents than their private counterparts. The loss in market shares is invariably linked to other important limitations at the sector level, most importantly low marketing budgets as well as failure to introduce new generic products at the pace needed to maintain as well as expand current market shares on the side of the public business sector.

The response of the subsidiaries of research-based companies reflected inaccuracy in terms of anticipated market outlook. Subsidiaries of research-based companies have been losing market share in Egypt. This loss of market share may in fact be a phenomenon which warrants concern by policy makers. As indicated earlier, the prices of products manufactured by subsidiaries of research-based companies in Egypt are relatively lower compared to a situation whereby these products were to be imported. Consumers are actually the key beneficiaries from these significant price differentials. Whether or not the decrease in market share, which has in fact run parallel to an increase in the market share of imported products, is an indicator that subsidiaries of research-based companies are shifting their supply to the market from locally manufactured to imported products in order to escape pricing rigidities in Egypt, is an issue which should warrant attention by policy makers.

Has your company encountered any difficulties in introducing new products as a result of enforcing EMR?

	Public	Private local	Private local with foreign equity
Yes	25.0%	18.2%	33.3%
No	75.0%	81.8%	66.7%
Total number of companies	4	11	3

Issues related to EMR have been on top of the lobbying agenda of local companies in building a case against the TRIPS Agreement since 1995. However, the majority of companies surveyed indicated that they have not encountered any problems in relation to EMRs since coming into force in 2000. These results run in line with actual evidence that EMRs has not been an issue of legal conflict on the Egyptian market.

Do you perceive a threat from TRIPS to <u>export</u> levels of local companies?

	Public	Private local	Private foreign	Private local with foreign equity
Yes	60.0%	63.6%	.0%	66.7%
No	40.0%	36.4%	100.0%	33.3%
Total number of companies	5	11	5	3

The majority of private sector companies surveyed indicated that they foresee a direct threat from the enforcement of higher standards of IPRs to their export volumes. In light of the fact that infringing activities on the Egyptian pharmaceutical market stand as low as 5 percent, this share seems to have been placed out of scale.

7.7 Summary and Conclusion

In this chapter I have attempted to provide an answer to the research question concerned with the impact of strengthening the country's IPRs regime in conformity with the TRIPs Agreement on pharmaceutical price levels in Egypt, as well as the market shares of key players.

This chapter, therefore, probed deeper into the costs associated with enforcing pharmaceutical product patent protection in Egypt as of January-2005, whereby costs have been narrowed down to the differential between what consumers actually pay for new originator products -which are protected by patents- and that they would have incurred in terms of prices and cost had generic products been available. This chapter relied on proprietary data concerning a selection of the top 42 therapeutic classes from IMS (accounting for 50 percent of Egypt's pharmaceutical market) in order to examine pharmaceutical market dynamics in Egypt during the period 2004-2008.

Results have indicated that in 14 of Egypt's top 42 study therapeutic classes, there was evidence regarding launches of new molecule by research-based pharmaceutical companies on the Egyptian market, with no evident generic competition. Together the 14 therapeutic classes account for 2 percent of the Egyptian pharmaceutical market by value, as well as 14 percent of the sample therapeutic classes.

Within the 14 therapeutic classes, which have been impacted on by the TRIPS Agreement, a total of 24 molecules have not been facing generic competition against brand-name products falling within their domain. Between 2004 and 2008, Egyptian consumers paid a total LE 605 million for products falling within the domain of new molecules, which faced no generic competition.

Of the total cost to consumers, some LE 126 million were incurred over products, which are not protected by patents, and yet have no visible generics competitors. These results indicate that the impact of the TRIPS Agreement has so far been relatively modest, compared to the overall market size. Of no less importance, the fact that it is not only patents that disallow generic competition warrants attention.

Chapter Seven also assessed the extent to which Egyptian consumers have been willing to trade-off lower prices of older drugs for more innovative new products. Results concerning shifts in market shares between old and new molecules have revealed important trends regarding consumer preference for new generation molecules within the scope of the country's top 42 therapeutic classes. In 15 out of some 24 molecules in which there has been no evidence of generic competition in Egypt between 2004 and 2008, consumer demand has been gradually shifting in favour of new products introduced. This shift has been occurring despite the fact that relative prices of new products were much higher than older generation molecules already present within the same therapeutic class. Market data has also indicated that between 2004 and 2008, the local private sector has maintained the position of the dominant player in 6 out of the 14 therapeutic classes which saw the introduction of patent-protected products. In addition, the private sector has consolidated its position in four classes in which it held a minority share. The same did not hold true for the public business sector, which has been losing share. This loss is, however, not necessarily attributable to the impact of the TRIPS Agreement, but rather to sector specific ownership related problems, which have not allowed this important segment of the manufacturing sector to invest sufficient resources needed to compete in what is becoming a highly aggressive market.

While the impact of the TRIPS Agreement has clearly been visible as reflected in the number of new products that have come to the market, with no generic competition, it is safe to argue that relative to the overall size of the market, this impact remains modest. Shifts in terms of consumer/prescribing physician's preference in favour of new versus mature molecules was, nonetheless, already underway. Such a shift has not yet been reflected in a full-fledged movement in market shares to the disadvantage of local companies. In fact the local private sector has been gaining market shares at a remarkably agile fashion.

The same, however, does not apply to the public business sector, which has been fast in terms of losing market share. It is important to highlight that such a loss in market share is not necessarily attributable to the TRIPS Agreement, but to the set of problems alluded to earlier in Chapter Three.

Survey results covering 25 companies operating on Egypt's pharmaceutical manufacturing scene, have indicated that evaluating perceptions regarding the future state of the business after full respect of pharmaceutical product patent protection in Egypt -as reflected in the responses of the various players- against actual market trends indicated lack of accuracy and flaws in judgment. The business energy of practically all companies operating on Egypt's pharmaceutical manufacturing scene has been dedicated to magnifying the threat of the TRIPS Agreement on their business, while neglecting another very important threat as manifested by impending increased import competition as well as the threat of being marginalised on the world production scene for not dedicating adequate resources to technological upgrades and to investments in R&D even at their most modest levels.

8. CONNECTING THE DOTS OVERVIEW OF THE RESEARCH AND KEY FINDINGS

8.1 Introduction

In this chapter, an overview of the research is presented in section 8.2. The contribution of the research to researchers and the debate on industrial policy is presented in section 8.3. The contribution of the research to policy is presented in section 8.4, and the limitations of the research and areas which warrant future research efforts are presented in section 8.5.

This thesis has been motivated by the debate concerning one important facet of government intervention in the economy, namely industrial policy. Industrial policy as structured differently in developed as well as in developing nations has invariably shaped their growth outcomes. The case study of Egypt's generics pharmaceutical industry provided an interesting avenue to contribute to the debate on industrial policy.

The fact that the development and expansion of pharmaceutical productive capacity has occurred within the context of protective non-tariff regulatory trade barriers, which have historically kept generics import competition at bay, is what rendered the case study of Egypt's generics pharmaceutical industry relevant to the debate on industrial policy. Examining the efficiency levels exhibited by this industry, as well as a host of attributes including export performance as well as relative prices, has been the angle through which the contribution to the debate on industrial policy has been planned. Additionally, the environment within which this industry currently operates has made the case study even more interesting. Under the context of the currently ruling regulatory and policy environment, the Egyptian pharmaceutical industry has been a prime candidate to be affected in a major way as a result of the country's process patent regime having given way to a product patent regime since January 2005. The gradual increase in generic import penetration, has also been levying significant competitive pressure on the local segment of this industry.

In retrospect, this thesis investigated patterns of 'association' between trade and industrial policies, the country's national pharmaceutical policy (including pricing), the pre-January

2005 intellectual property rights regime, productivity and productivity growth in the Egyptian generics pharmaceutical sector. This thesis also compared relative prices on the Egyptian pharmaceutical market and the extent to which consumers have been able to fully capture the benefits associated with having access to the largest generics manufacturing base in the region. This thesis took the first attempt to quantify the actual burden on consumers as a result of enforcing higher standards of IPRs in conformity with the TRIPS Agreement on Egypt's pharmaceutical market.

The following research questions have been posed and answered by the research:

- To what extent have mechanisms used to protect and regulate the Egyptian pharmaceutical industry been associated with productivity growth?
- To what extent has there been evidence of productivity dispersion in the Egyptian pharmaceutical industry in accordance to ownership, and output orientation?
- How far and in what ways have the regulatory framework(s) governing this industry allowed local generics companies to charge higher than average prices compared to other world markets?
- What has been the impact of strengthening the country's IPRs regime in conformity with the TRIPS Agreement on pharmaceutical price levels in Egypt, the associated cost to consumers, as well as on the market shares of key players?

In light of the above research questions, this thesis has managed to contribute to a diverse set of academic literature, as well as provide valuable policy guidance.

First, the estimation of firm-level productivity growth under a protectionist regulatory regime has been one important avenue to contribute to the literature on industrial policy (evaluating productivity growth under a protectionist trade and regulatory regime).

Second, the verification of whether there has been evidence of firm-level productivity dispersion in relation to ownership and output orientation in Egypt's generics pharmaceutical industry has provided guidance to policies dictating the pace and nature of

privatisation policies, as well as to policies which aim at diluting excessive inward orientation and soliciting increased export-penetration.

Third, and in light of the absence of research on relative prices on the Egyptian pharmaceutical market, this thesis has contributed to the evaluation of the extent to which the country's pharmaceutical policy -including pricing- has been successful in terms of ensuring the prevalence of fair prices to consumers. By undertaking this analysis, the thesis has been able to contribute to the body of literature which examines the nature and determinants of relative prices on pharmaceutical markets.

Fourth, an important contribution of this thesis has been in the area of quantifying the impact of the TRIPS Agreement in terms of cost to consumers on Egypt's pharmaceutical market. Using real market data, empirical results have provided valuable policy guidance, particularly in terms of throwing light on the nature of policy interventions which are needed in order to protect low-income consumers against the impact of catastrophic health care expenditure as it pertains to pharmaceutical needs. Empirical results contribute to the body of literature concerned with evaluating the impact of the global harmonisation of IPRs in the domain of the pharmaceutical industry in emerging markets.

8.2 Overview of the Research and Summary of Key Findings

The following sections present the summary of the thesis chapters, as well as the key findings.

Following the introductory Chapter, Chapter Two presented the review of the literature on industrial policy, which embraced a wide continuum of policy options, ranging from free trade to protectionism as two extreme poles. Various incentive measures such as tax holidays, extending subsidized credit facilities, state-led investments in training and re-training, provided by governments to solicit certain outcomes also fall on this wide continuum. How and why have the industrial policy choices made by governments differentially elevated some of the developing nations to the status of newly industrialized countries (NICs), while others have lagged behind, is perhaps the most important of

insights to be derived from this body of literature. It is safe to argue that the empirical evidence concerning the outcome of industrial policy choices in various parts of the world has fueled rather than resolved the debate concerning what an optimal industrial policy should be.

While the neoclassical paradigm, which propagated minimal involvement of governments in economic activity and the supremacy of the rules of comparative advantage in dictating specialization has dominated during the aftermath of World War Two, the Prebisch-Singer Thesis regarding the secular decline in the terms of trade of industrial versus primary commodities has managed to elevate import-substitution-industrialization as the preferred policy option by the majority of developing nations eager to achieve rapid industrial growth and diversification, particularly during the 1950s and 1960s.

The infant industry argument has heavily influenced industrial policy in most -if not all- developing nations. The case of Egypt was no exception. Governments chose to erect tariff barriers to shield their nascent industries against import competition, with the objective of altering static comparative advantage in the production and trade of primary commodities. During the debt crisis of the late 1980s, neoliberalism, nonetheless, challenged the basic foundations of the import-substitution paradigm, by providing mounting evidence that protection has retarded productivity growth rather than supported it. Evidence has been provided from Latin American countries, that the total exclusion of export promotion strategies subjected them to the brunt of external shocks triggered by rising oil prices, while their protected manufacturing industries have not able to capture any shares of significance on export markets or withstand competition on local markets.

The review of the literature also provided the interesting case of the first tier of NICs, accordingly enriching the literature on industrial policy with a new model which blended import-substitution with export promotion strategies. In this respect, import-substitution-industrialization and export-led growth were never mutually exclusive options for industrialization for the NICs. Policy interventions in the NICs provided subsidized credit to selected industries, protected domestic and import substitutes and made public

investments in applied research on condition that firms met industry-specific export targets. Import-substitution-industrialization and export-led growth were never mutually exclusive options for industrialization for the NICs.

The rich set of country experiences, documenting the outcomes of various industrial policies has, nonetheless, not finally resolved the debate concerning what an optimal industrial policy should be.

Chapter Two also presented the concept of efficiency, as well as the underlying reasons behind differential efficiency/productivity outcomes among various countries/ industries/ firms. The literature has indicated that variances in observed productivity levels may arise from a plethora of sources. Trends in TFP may mirror the efficiency of a particular reform program, learning effects, the deployment of new generations of technology, technical know-how, organizational skills, enterprise response to changes in competition and other related aspects of market structure. In addition, TFP trends may also reflect the impact of social, political and institutional obstacles to potentially useful innovations. However, it has remained difficult to ascertain the causes of productivity movements (Jefferson, Rawski and Zhend, 1996: 147).

Chapter Two, provided the review of the literature on industrial policy as well as conceptual framework needed to contribute to the debate on industrial policy through examining the growth trajectory and key performance attributes of Egypt's generics pharmaceutical industry.

Chapter Three presented the salient characteristics of the pharmaceutical industry, with the objective of highlighting the key differences between research-based and generics pharmaceutical manufacturers, as well as the structure of the world pharmaceutical market, in terms of both production and trade. The objective of this review was to be able to identify how different countries/companies have been defining and accordingly establishing their specialisation in the domain of the pharmaceutical industry, from the perspective of presence on the world production and trade scenes. Chapter Three also examined in detail

the growth trajectory of Egypt's generics pharmaceutical industry against the nature of the industrial policy regime, which ruled during the study period. The key objective was to provide the background against which some of the performance attributes of this industry were to be highlighted, as well as provide the context to address the research question concerning the extent to which mechanisms used to regulate and protect the Egyptian generics pharmaceutical industry have been associated with productivity growth.

Chapter Three explained how the presence/absence of the basic scientific infrastructure in universities, government research institutes and within industry has initially dictated an international divide, whereby developed countries specialised in the production and trade of single-source products, while developing nations focused on multiple-source drugs. It has been highlighted that small generics companies have, nonetheless been capable of contributing to the drive for innovation in the domain of the pharmaceutical industry. This is particularly true with respect to the 'discovery' phase of new drugs, where it has been demonstrated that generics companies can discover new drugs with minimal investments. The emergence of China and India as two key players on the world generics pharmaceutical production and trade scenes has also been a key highlight of Chapter Three. Upgrading technological capabilities, engaging in pharmaceutical R&D, as well as a succinct drive to support export penetration have proved to be significantly important in elevating some companies in emerging markets to the status of key players on the global pharmaceutical scene. It was on all these fronts that the Egyptian generics pharmaceutical industry performed below-par compared to its competitors in other emerging nations, most notably in India and Jordan.

Chapter Three provided evidence that since the formative years of the Egyptian generics pharmaceutical industry, and passing through different policy and regulatory regimes, the focus as well as the key criteria for success for this industry has primarily been on increasing the levels of self-sufficiency, in what has been regarded as a strategic sector. The various shifts in economic policy direction, as well as episodes of institutional and regulatory reforms have consistently defaulted in shifting the relatively excessive inward orientation of this industry.

Chapter Three documented the extent to which the key changes in Egypt's industrial policy regime during the study period have been primarily concerned with addressing institutional as well as regulatory issues such as public sector reform, privatisation, and price liberalisation. None of these pillars of reform impacted the generics pharmaceutical industry in a positive way, in terms of creating the right environment for export growth, for efficiency enhancement and for technological advancement. A key limitation of Egypt's industrial policy as implemented within the domain of the generics pharmaceutical sector and as contrasted against the review of the literature presented in Chapter Two, was that it failed to clearly tie up regulatory protection to performance outcomes such as exporting levels, as well as advancing technological capabilities. The outcome of this policy pitfall is that Egyptian generics companies have been outpaced by their counterparts in other parts of the emerging markets, such as with the case of India. Indian companies have emerged at a far more advantageous position when it comes to competing on what is turning to be a highly aggressive global pharmaceutical market.

To date, non-tariff regulatory trade barriers remain to be manifested in the extent to which registration procedures facing imported products -as administered by the Ministry of Health- are made both stringent and cumbersome for generic products. The most important pitfall of the reform program as applied during the 1990s, was that by maintaining non-tariff regulatory barriers in the domain of the pharmaceutical industry, modest results have been achieved in terms of instigating the needed export supply response from this sector of manufacturing activities. The captive consumer market of some 80 million inhabitants, proved to be more attractive to generics companies than the relatively challenging pharmaceutical export market.

In Chapter Three, it has been argued that starting from the early 1960s, and passing through the major policy shifts of the 1970s, 1980s and 1990, Egypt's pharmaceutical industry was targeting the attainment of one key objective, namely improving the levels of self-sufficiency. Reaching high levels of self-sufficiency became one of the most important indicators of success from policy makers' perspective. With the pharmaceutical industry

meeting 81 percent of local demand by value, the attainment of equally important objectives such as penetrating export markets, achieving technological advancment and investing in R&D proper have been overshadowed. These three limitations have in in fact been the key pitfalls of the reform programme and the industrial policy regime which remains to govern the pharmaceutical industry. These pitfalls have proved to be in sharp contrast to the successes attained in East Asia, as a result of tying up protection from import competition, to expanding presence on the export front. The experience of Indian generics companies, also falls in marked contrast to the case of Egypt. The performance of India's giant pharmaceutical company Ranbaxy is a case in point. Unlike Egyptian generics companies, Ranbaxy established international presence and operations in 40 countries, and manufacturing facilities in 6 countries, with export sales also accounting for 50 percent of total output (Ranbaxy, 2009). India's generics companies have assumed this advantageous position as a result of the government creating a home environment which has forced firms to improve their technological capabilities (Mourshed, 1999).

Privatisation as implemented in the domain of the pharmaceutical industry was also circumscribed by allowing the private sector to only hold minority stakes in public business sector companies. Maintaining majority ownership by the state has been specifically designed to relegate the full pursuit of profit maximisation to secondary importance. In spite of legislative changes such as Public Business Sector Law 203 of 1991, state-owned pharmaceutical companies have not been able to award priority to achieving higher levels of profit maximisation as well as economic efficiency. Relatively low profitability levels have obstructed adequate investments in upgrading technological capabilities. These companies remained to be held captive under state ownership, to realise the social objective of providing affordable drugs to the Egyptian population at large.

The liberalisation of pharmaceutical prices also proved to be resilient to reform. While the cost-plus pricing system does ensure a positive returns to all manufactures, the fact that this industry imports the bulk of its raw material inputs has rendered it particularly sensitive to exchange rate fluctuations. While all companies operating on the Egyptian pharmaceutical market have been negatively impacted by pricing rigidities, public business sector

companies have been particularly vulnerable to the rigidity in adjusting pharmaceutical prices to accommodate for inflation and foreign currency movements, because most of their products have been priced during the 1960s and 1970s with marginal flexibilities in price adjustments. This rigidity has levied a heavy toll on their profitability levels and hence their subsequent abilities to both modernise their plant and equipment as well as to engage in significant marketing initiatives. The private sector has also been facing the same constraint, yet at a relatively less disability magnitude compared to the public sector.

The outcome of such an environment was that while Egypt's generics pharmaceutical industry has managed to successfully close down on the levels of self-sufficiency, it has consistently failed to contribute to export growth at any level of significance. Transcending the boundaries of engaging in sheer pharmaceutical formulation activities and venturing towards expanding R&D capabilities is also one of the most visible outcomes of the aforementioned policy and regulatory environment. Some of the local companies (such as EIPICO for example) have, nonetheless, achieved remarkably high export-to-output ratios.

In Chapter Four, I presented the key components of the national drug policy in Egypt, with the objective of throwing light on the characteristics of the pharmaceutical regulatory regime as it has been influencing relative prices on the market. Chapter Four has been structured to provide the background against which the research question concerning relative price levels on Egypt's pharmaceutical market has been addressed.

Chapter Four examined the pharmaceutical industry in the context of the Egyptian health care system and how it "interacted" with it, both from a formal perspective (covering the costs and purchasing of medicines by the state/health system) and from the perspective of patients through direct purchases outside the remit of the health system. The objective has been to place the findings concerning relative price levels in the context of 'who' shoulders the burden of pharmaceutical expenditure in Egypt.

Among the key findings of Chapter Four is that while the Egyptian government has been endeavoring to extend the benefits of social health insurance to the maximum number of

beneficiaries, Egypt's health care system remains largely inequitable, leaving close to half of the country's population to be fully vulnerable to potential catastrophic health care expenditure.

Of equal importance from a policy stance, and despite the fact that Egypt has the largest generic manufacturing base in the Middle East and North Africa region, as well as the largest consumer market, the review of the country's health care system and pharmaceutical regulatory regime indicated that a clear and coherent generics policy remains to be largely absent. This absence raised concern in light of the fact 68 percent of expenditure on drugs remains to be shouldered by out-of-pocket expenditure. The exclusion of pharmaceutical products from patentability, was perhaps the most "easy to capture" component of supply-side related generics policy in Egypt. Such exclusion from patentability has primarily targeted supporting access to affordable drugs rather than supporting the pharmaceutical manufacturing base from an industrial policy perspective. While a 20-year period of pharmaceutical patent protection has been enforced in Egypt since January 2005, Bolar-kind of practices are, nonetheless, allowed under Patent Law 82 of 2002, in a clear stance of supporting generics penetrate the market once a patent expires. Marketing authorization in Egypt, however, remains to be largely indifferent as to whether or not a product is an originator brand or a generic product, particularly from a timeframe perspective. In other words, generics do not follow an accelerated track for obtaining marketing authorisation.

Supporting the penetration of generics by verture of a lax patent regime has been a key "undeclared" component of generics policy in Egypt. However, becuase such support has been not matched with clear policies which target iliciting increased demand for gnerics on behalf of prescribing physisians, insurares and consumers, the outcome has not been effective in any major way. This has been the actual case in Egypt. To date the retail market, which caters to the largest demand base, remains to operate without clear policy guidelines with regards generic policy. In the domain of private health care services, where the scope of the associated retail pharmaceutical market stands in excess of LE 13 billion, there is no formal policy on promoting generic prescription. While in 2008, generics accounted for 50 percent of Egypt's retail market by value, local generic companies have

often complained that the marketing budgets of research-based companies, as well as first-movers in the generics market are relatively large. In light of the fact that direct-to-consumer pharmaceutical advertising in Egypt is prohibited by law, these large marketing budgets have been translated into more frequent sales visits per physician as well as a larger number of free samples for giveaways which directly influence market shares. Additionally, while the share of generic pharmaceutical products listed on the reimbursement (positive) list of key institutional insurers such as the HIO, as well as for MOH tenders is larger than the share of originator products, the demand base of these two largest institutional consumers of medicine in Egypt remains to be relatively small.

Generic substitution in pharmacies is not formally supported from a formal policy perspective, nor is it common practice in Egypt. While dispensing pharmacists in private pharmacies often propose alternatives to products which may not be available, this practice is rarely exercised in a systemic method to relieve patients from paying higher prices for originator/brand-name drugs by proposing generic substitutes.

With regards requirements for co-payments towards the cost of drugs for the three largest groups of beneficiaries under the umbrella of social health insurance, differential co-payments to promote generic drugs remain to be absent. In other words, generics do not attract lower copayments compared to the branded version of the same medicine.

The fact that no more than four identical products in terms of therapeutic value and dosage forms are allowed sale on the local market is one of the key policy limitations to enhancing price competition on Egypt's generics market.

Chapter Four, therefore, provided the necessary context against which the research question concerning relative price levels on Egypt's pharmaceutical market was to be addressed. In this respect, Chapter Four has set the scene to examine in more detail, and based on real market data, the nature of price competition between various products on Egypt's pharmaceutical market and the extent to which consumers (patients) have been able to

capitalize fully on the cost advantage of having access to a large generics medicine manufacturing base.

In Chapter Five, the two research questions concerning the extent to which mechanisms used to protect and regulate the Egyptian pharmaceutical industry been associated with productivity growth and the nature of productivity dispersion in the Egyptian pharmaceutical industry in accordance to ownership, and output orientation have been addressed.

Chapter Five started with presenting the methodology to estimate TFP growth in Egypt's generics pharmaceutical industry during the period 1993-2005, for which data was available. The details of the non-parametric, frontier methodology known as data envelopment analysis (DEA) to obtain the Malmquist productivity index at the firm-level for a representative sample of firms operating in the Egyptian pharmaceutical industry was also presented in detail. The key empirical findings presented in Chapter Five indicated that the best-practice firm in terms of TFP change belonged to the private sector, while the laggard firm belonged to the state-owned public business sector. In addition, no differences of major significance existed between the performance of private sector and state-owned generics companies. State-owned companies which have been subject to partial privatization did not exhibit higher levels of TFP change compared to those which remained under full state-ownership. Under the protectionist regime which shielded generics companies from import competition, empirical results indicated that mean TFP change for the sample firms throughout the study period (1.01) exceeded the mean TFP change for all Egyptian industries (0.75), and that there was evident disassociation or weak correlation -at best- between productivity growth and the degree of export orientation.

While there has been empirical evidence regarding positive TFP growth in Egypt's pharmaceutical industry (for these ample firms), under the ruling -relatively protectionist- regulatory regime, which has historically kept generics import competition at bay, this should not be judged to be a healthy phenomenon. Protectionism may have supported this industry to survive during its formative years, especially since there has been ample

historical proof of the unequal and possibly detrimental competition with foreign companies during the 1930s (Handoussa, 1974). Had Egyptian policy makers supported a free trade regime, and eliminated non-tariff regulatory trade barriers in the domain of the pharmaceutical sector beyond the 1930s, it is most likely that Egypt would not have had a local pharmaceutical industry of the magnitude which is currently present.

While efficiency levels seem to be respectable compared to Egypt's manufacturing sector at large, protracted non-tariff regulatory barriers in the domain of the generics pharmaceutical industry in Egypt has ran parallel to prolonging its inward orientation. The relevant question which came to mind was related to why has an industry that was relatively efficient compared to other sectors of manufacturing activity in Egypt not been exploiting export markets to further support growth in output and associated profitability. The answer has actually been provided in Chapter Six. If this industry has been successfully able to charge atypical prices compared to standard generic-to-originator price ratios prevalent in other world markets, then why venture on the tough track of exporting.

In addition, there is evidence that pharmaceutical exports are made cumbersome due to the high cost of registration fees with the regulatory authorities in export markets, not to mention having to compete with heavy weight generics manufacturers such as India and China. It has also been often argued by industrialists operating in this sector that exporting in the case of pharmaceuticals also involved *atypical* costs, whereby pharmaceutical registration procedures in importing markets sometimes involve expenses which may go as high as USD 200,000 thousand for a single product, with no grantee that the product will eventually obtain the registration license. This has been judged to be one of the reasons behind the absence of positive a correlation between productivity growth and outward orientation.

If the local market is large enough to support output growth and is profitable -if not more so- enough compared to export markets, then there is little incentives for companies to actually export.

The absence of a positive correlation between export orientation and TFP growth must, however, be interpreted with caution. As explained earlier, because of pricing rigidities, which have in fact been present during the entire period which saw the rise of Egypt's modern generics pharmaceutical industry, some companies have limited exports to products, which in their judgment, reflect fair pricing and hence fair profitability levels. In light of rigid price readjustments to accommodate for inflation and currency devaluation, some local companies have intentionally excluded a large segment of their product portfolio from being exported. Because importing markets stipulate that import prices should reflect the same prices on the local markets, there have been little incentives for these companies to actually export products on which they incur very low profitability/losses to risky export markets.

Chapter Six provided a brief review of the literature on the nature of competition on the pharmaceutical market, thus setting the scene to address the research question concerning relative prices of pharmaceuticals on the Egyptian market. In major world markets, when 10 firms manufacture and distribute generic versions of a particular drug, the generic retail price of this drug falls to an average of 60-34 percent of the brand-name price. With 20 manufacturers, the generic price may well go to 20 percent of the brand-name price (CBO, 1998).

Because it was not feasible to examine the prices of all generic products relative to originator products on the Egyptian market, and based on the WHO/HAI (2006) methodology, the evaluation was confined to the list of 21 molecules operating in the domain of 14 therapeutic classes. The 21 study-molecules account for 4.4 percent of Egypt’s pharmaceutical market, and involved competition between some 196 products.

The examination of price competition on Egypt’s pharmaceutical market indicated that for the sample molecules, generic-to-originator prices have been found to be higher than the standard ratios observed in major world markets. Of no less importance, generic diffusion has not necessarily been bringing down average prices. Evidence was also presented that prescribing habits have resulted in a situation whereby the least priced generics were not

necessarily the most prescribed. A key finding was that in only 4 out of the 18 study molecules (3 molecules have been excluded because there was no originator brand to compare with), the price of the examined list of generic equivalents went below the 50 percent threshold of the price of the originator brand. What was even more important to note, has been the finding that in roughly half of the cases, the prices of generic products which were late market entrants, exceeded the price of originator products or the first market entrant in the therapeutic class. This observation was evident in the case of 9 out of 19 sample-molecules which qualified for examination.

An equally important finding presented in Chapter Six, is that by examining prices in conjunction with the rate of generic diffusion for the sample molecules, is was evident that generic diffusion did not significantly bring down average prices on the Egyptian market. The prices of subsequent market entrants were found to be clustered around the price of the first market entrant. With only one exception, for products competing within the domain of the 21 molecules, the prices of subsequent market were either clustered around the first entrant, or went above it.

Chapter Six also presented an evaluation regarding the extent to which Egyptian consumers (patients) have been capitalizing fully on the cost advantage of a highly genericised market. The prices and market shares of originator products were compared to those of the most sold generic and the least priced generic within the domain of the study molecule. Results indicated that of 21 study-molecules, in only 2 cases were the most sold generic also the least priced generic. In roughly half of the molecules examined (10) the single largest product market share was held by the originator brand(s).

These results indicate that pricing policies in Egypt need to be revised to induce a visible downward trend regarding relative prices for new generics market entrants, similar to observed patterns in major world markets. There is a visible need for a generics prescribing policy in Egypt, whereby the physician is to prescribe by generics name and the dispensing pharmacists becomes obliged to dispense the least priced generic, unless otherwise not allowed due to valid medical reasons. This need is made all the more pertinent, in light of

the upward pressure on prices as a result of enforcing pharmaceutical product patent protection in Egypt, as detailed in Chapter Seven.

Since 1995, the impact of the TRIPS Agreement on Egypt's pharmaceutical industry has been one of the key concerns of industrialists, policy makers as well as consumers alike. However, no attempt has been made to make use of real market data to place accurate numbers on the bill associated with strengthening the country's IPR regime starting with the date of enforcing pharmaceutical product patent protection in January 2005.

In Chapter Seven, having access to IMS data for Egypt allowed for providing accurate numbers with regards to the toll associated with the TRIPS Agreement, both from a demand side perspective by looking at overall prices, as well as from a supply side perspective by examining shifts in market shares between the various players on the Egyptian market.

Chapter Seven began by documenting why IPRs issues have been included on the agenda of the Uruguay Round as well as, highlighting the concerns raised around the price implications of the TRIPS Agreement, particularly from the perspective of consumers of pharmaceutical products in developing countries. The Doha Declaration on the TRIPS Agreement and Public Health eventually came against a background of evidence regarding the fact that the global harmonization of IPR standards sharply curtailed the traditional capacity of suppliers of some of the public goods, such as in the case of health care to properly address priority needs of the less affluent members of society, particularly in the case of developing countries. The Doha Declaration was in fact the first acknowledgment by the WTO of the potential adverse 'effects on prices' of the enforcement of higher standards of IPRs in the domain of pharmaceutical production in developing countries. It was the concern about the adverse 'effects on prices' that motivated the investigation concerning the quantification of the impact of the TRIPS Agreement on Egypt's pharmaceutical market.

Chapter Seven also presented the highlights of Egypt's IPRs regime. Patent Law 132 of 1949, which ruled up to 2002, emerged as one of the most consistent denominators which characterized Egypt's pharmaceutical policy regimes during the 1950s, 1960s, 1970s, 1980s and 1990s. Law 132 of 1949 excluded pharmaceutical products from the framework of patents, thus ending the generous privilege enjoyed by generics pharmaceutical companies, to manufacture products which were still under patent protection in major world markets. In 2002, the new Patent Law 82 introduced pharmaceutical product protection for the first time in Egypt, and enforced it as of January 2005.

The costs associated with enforcing pharmaceutical product patent protection in Egypt as of January-2005 were quantified in Chapter Seven. Costs have been narrowed down to the differential between what consumers actually pay for new originator products -which are protected by patents- and what they would have incurred in terms of prices had generic products been available. Survey results, which covered 25 of Egypt's key players on the pharmaceutical market, including public business sector companies, local generics manufacturers and subsidiaries of research-based pharmaceutical companies concerning their forecasts regarding the impact of the TRIPS Agreement on their business, were also presented in Chapter Seven.

A first step was to identify new products which have not been facing generic competition on Egypt's pharmaceutical market. Because it was not possible to study the whole market (600 therapeutic classes), the focus was narrowed down to the therapeutic classes which accounted for 50 percent of the Egyptian retail market. Results indicate that in 14 of Egypt's top 42 study therapeutic classes as identified through IMS, there was evidence regarding launches of new molecule by research-based pharmaceutical companies on the Egyptian market, with no evident generic competition. Together the 14 therapeutic classes account for 2 percent of the Egyptian pharmaceutical market by value, as well as 14 percent of the sample therapeutic classes.

Within the 14 therapeutic classes, which have been impacted on by the TRIPS Agreement, a total of 24 molecules have not been facing generic competition against brand-name

products falling within their domain. Between 2004 and 2008, Egyptian consumers paid a total LE 605 million for products falling within the domain of new molecules, which faced no generic competition.

Of the total cost to consumers, some LE 126 million were incurred over products, which are not protected by patents, and yet had no visible generics competitors. These results indicate that the impact of the TRIPS Agreement has so far been relatively modest, compared to the overall market size. Of no less importance, the fact that it was not only patents that disallow generic competition warrants attention. Based on the sample molecules presented in Chapter Six, because generic-to-innovator prices in Egypt proved to average 73 percent, the actual cost of imposing a 20-year period of pharmaceutical patent protection as of January 2005 can then be calculated as the wedge between what consumers paid for new products which had not generic equivalents and what they would have incurred had generics been available on the market. The actual cost to consumers then becomes the relatively smaller value of LE 129 million during the period 2004-2008.

Chapter Seven also assessed the extent to which Egyptian consumers have been willing to trade-off lower prices of older drugs for more innovative new products. Results concerning shifts in market shares between old and new molecules have revealed important trends regarding consumer preference for new generation molecules within the scope of the country's top 42 therapeutic classes. In 15 out of the 24 molecules in which there has been no evidence of generic competition in Egypt between 2004 and 2008, consumer demand has been gradually shifting in favour of new products introduced. This shift has been occurring despite the fact that relative prices of new products were much higher than older generation molecules already present within the same therapeutic class. Market data has also indicated that between 2004 and 2008, the local private sector has maintained the position of the dominant player in 6 out of the 14 therapeutic classes which saw the introduction of patent-protected products. The same did not hold true for the public business sector, which has been losing share. This loss is, however, not necessarily attributable to the impact of the TRIPS Agreement, but rather to sector specific ownership related problems, which have not allowed this important segment of the manufacturing

sector to invest sufficient resources needed to compete in what is becoming a highly aggressive market.

By contrasting the results of the survey, which covered 25 of Egypt's pharmaceutical companies, against actual market data, significant flows in perceptions regarding the future state of the business were detected. On one front, the viewpoint of the local private sector, concerning a negative impact of the TRIPS Agreement on their ability to introduce new products and hence the loss of market shares was not in consistency with the increase in the market shares gained by the local private sector between 2004 and 2008. The opposite held true for subsidiaries of research-based companies, who have lost market shares during the same period. The situation of the public business sector is more complex. While the public business sector companies surveyed correctly anticipated a loss in market share, this is not necessarily a reflection of a negative impact of the TRIPS Agreement, but rather a reflection of a combination of factors, which have been slowing down the ability of this segment of the manufacturing sector from keeping up with the private sector, be it local or foreign. Public business sector companies suffer from ailing plant and equipment, relatively scarce marketing resources, and a legacy of meeting social rather than pure profit maximization objectives. Any one of these factors alone is sufficient to impact negatively on market shares.

After having placed together the 'mosaic' of findings, the actual contribution of this thesis has mainly been in the domain of providing in-depth insight to the subject matter of competition on Egypt's pharmaceutical market, the extent to which Egyptian consumers are deriving real benefits from having access to one of the largest pharmaceutical manufacturing facilities in Africa and the Middle East, the impact of the TRIPS Agreement on this sector, and the levels of efficiency exhibited by local generics companies under what is clearly a relatively protected market.

8.3 The contribution to the research to researchers: the debate concerning protectionism

It has often been argued that the debate surrounding ISI and protectionism is 'old', meaning that this debate has been largely resolved in favor of the neoclassical/neoliberal paradigm of openness and free trade, particularly with the ascendency of the WTO during the mid-1990s. With protectionist sentiment being still visible in many parts of the world, including the industrialized countries, there is no doubt that this debate is still alive.

From an efficiency perspective, and taking efficiency at the manufacturing sector-wide level in Egypt as a bench-mark for comparison, it was evident that an industry can be protected, yet exhibit positive productivity growth as well as relatively healthy efficiency levels. The caveat, which however remains, as has been alluded to earlier in relation to the limitations of DEA, is that by restricting relative comparisons to Egypt, it is possible that all pharmaceutical firms covered in the thesis, as well as Egypt's manufacturing industries at large could be inefficient, but with some being relatively less inefficient than others.

The case of Egypt's pharmaceutical industry also provided several important contributions to the debate concerning the merits of industrial policy as manifested in interrupting free trade by virtue of imposing regulatory trade barriers, which have in fact entrenched ISI beyond its formal demise as a policy direction in Egypt. During the very early years of this industry, and precisely during the 1930s, had free trade ruled, Egypt would not have had a pharmaceutical manufacturing base. Cut-throat competition as documented by Handoussa (1974), would have killed this infant industry in its cradle. However, what held true during the 1930s, does not necessarily hold true beyond the 1980s. While the private sector, which emerged during the 1980s and beyond proved to operate at relatively respectable levels of efficiency, it was clearly taking advantage of the captive local market as well as the absence of pharmaceutical product patent protection to drive up prices beyond standard world generic-to-originator prices as evident in the sample molecules. The consumer, who pays his/her pharmaceutical bill out-of-pocket is the ultimate loser from this protectionist formula. This protectionist formula is even harsher in light of the fact that the national drug policy in Egypt provides no clear guidelines to the private health care sector to either

promote generic prescription, nor to allow generic substitution by the dispensing pharmacists of the least priced generic available.

8.4 Contribution of the research to policy makers- practical contribution

The policy implications in relation to the key findings of this thesis are focused on the three areas of industrial policy, pricing policy and generics policy.

On the manufacturing front, public business sector pharmaceutical companies have been bearing the full brunt of acting as the social arm of the state in terms of the provision of low-priced pharmaceuticals. This situation has remained unchanged, in spite of the institutional and legislative change brought about by the ERSAP as early as 1991. By interviewing public business sector managers, it was repeatedly expressed that maintaining the policies of the pre-reform period has impacted negatively on the profitability levels of these companies, and hence their ability to invest in technological upgrades, needed to support higher levels of efficiency. Privatization alone has not been a panacea, as the performance of companies, which have been subject to partial privatization did not indicate significant differences in efficiency levels compared to companies, which have remained under full state ownership. Ensuring affordable medicine can be achieved through many channels, which do not jeopardize manufacturing efficiency as well as overall market health. One option, though a long-term one is to strengthen the outreach of the social health insurance scheme in terms of scope as well as coverage of pharmaceutical needs. This option, will grant these manufacturing entities breathing space to advance in the right direction in terms of sharpening their competitive abilities.

Another important policy message is related to the observed levels of export performance. While it held true that the Egyptian market has been relatively shielded from generic import competition, there has been evident infiltration of generics imports, with the expectation that a more aggressive generics import penetration stance is inevitable. For local generics companies to secure acceptable levels of turnover and profitability, exporting is no longer an option, it has become imperative for survival. The state has an important role to play, by supporting the efforts of local companies to overcome regulatory hurdles in export markets.

Government-to-government collaboration on this front has proved to be successful in terms of supporting the export drive of the local pharmaceutical industry, as has been documented in the case of Jordan.

On the price competition front, while local companies have been complaining of the rigidity of the pricing system, it was evident, that generic products need a new pricing formula to ensure that prices align with standards world generics-to-originator ratios. Of no less importance, the option of obliging physicians to prescribe on the basis of the generic rather than the brand-name will gradually allow the least-priced-generic to emerge as the most-sold-generic. In light of the fact that close to half of Egypt's population do not have access to health insurance schemes, policy interventions, which aim to alleviate hardship on consumers, should be prioritized.

While it was evident that the TRIPS Agreement was already impacting on consumers in terms of increased relative prices of new products, which have been facing no generics competition, it is safe to argue that the impact has been relatively modest, compared to the overall size of the market. This, however, does not mean that policy implications should be absent. The price impact is gradually building up in terms of potentially adding hardship on the uninsured masses, and a safety net, which is to support low-income consumers has to be structured as early as possible.

8.5 Limitations and areas for further research

One of the key limitations of this research has been related to the number of pharmaceutical companies covered, as well as their sectorial affiliation. The results would have been more robust, and findings more solid, had there been access to data from a larger number of companies. The fact that the public business sector accounts for the largest number of companies in the sample is also one of the key limitations. As highlighted earlier, the public business sector suffers from a plethora of weaknesses, which are invariably reflected in performance and efficiency levels. This has definitely brought down the bar in terms of relative efficiency levels, compared to a sample in which a larger number of private sector companies would have been present. Adding subsidiaries of research-based companies to

the sample, would again have provided another important and interesting dimension to the analysis. It is, however, important to mention that data availability in Egypt remains to be a serious impediment to the research community. Obtaining access to primary company level data, for 13 companies, for the relatively long study-period was considered a relatively commendable achievement.

An equally important limitation, was that Egypt has been the sole focus of analysis when it came to evaluating efficiency levels. Had access to company level data from comparator countries been available, again the research would have taken another interesting angle, by placing the findings in a comparative country perspective. Comparison would have in this case focused on the ruling policy and regulatory regimes in the two comparator countries which host a generics pharmaceutical industry, and then looking at respective performance in light observed differences in the ruling regimes as well as consequent performance outcomes.

Another limitation, which may impact on the focus of this thesis, is related to the fact that while one industry has been covered, the issues raised may be divergent, with each of the research questions in-and-of itself warranting separate research. What has been attempted in this thesis was to bring the diversity of issues under the one umbrella of the regulatory and policy regimes governing the pharmaceutical industry in order to simplify the reach approach and make the findings more relevant and coherent.

It is these limitations that open the door for areas of future research. Each of the core chapters of this thesis, may stand as an area of more focused research by widening the sample size and hence having more generalizable findings. The impact of the TRIPS Agreement is an area which warrants additional future focus by researchers. IMS data provides researchers with a rich database to analyses the impact of the Agreement on the entire market and hence possibly providing more targeted policy interventions based on impact on individual therapeutic classes in conjunction with the epidemiological scene in Egypt.

Comparing efficiency levels in the Indian generics pharmaceutical industry to the Egyptian counterpart, is one important avenue for future research. Access to data, however remains to be an important impediment. One angle to overcome this impediment, is to present the analysis on the sector-wide level versus the firm-level. For example, data needed to estimate TFP growth in India's pharmaceutical industry is actually available through India's Statistical Agency, while Egypt's data is available from the Central Agency for Public Mobilization and Statistics. The two country comparison will provide new insight to the issue of regulatory protectionism in relation to efficiency levels, as generic import penetration in India is also fairly absent, yet its generics industry has practically penetrated the world's most important markets.

ANNEXES

Annex 1

List of Interveiwees and Their Professional Affiliation

Dr. Ali Mohammad, Managing Director, CID, May 2004
Dr. Gala Ghorab, Director, Drug Holding Company, April 2004
Dr. Gamila Moussa, Director, Central Pharmaceutical Afairs, MOH, March 1999
Dr. Hossam AbouElEnein, Busniess Development Manager, SEDICO, May 2004
Dr. Hussein Zewail, Director, Al-Kahira Company, March 1999
Dr. Magdy Hassan, Chairman, Drug Holding Company, January 2006
Dr. Mohamed Roushdy, Regional Deirector, Pfizer Middle East, March 1999 and April 2004
Dr. Negad Sharawi, Former CEO GlaxoSmithKlein Egypt, April 2004
Dr. Samia Saleh, Director, Drug Planning and Policy Center, May 2007
Dr. Tharwat Bassily, Founder and CEO Amoun, January 2004
Mr. Ahmed Saleh, First Undersectreaty, Minsitry of Industry, February 1999
Mr. Khaled Nosseir, Chariman, Alkan, May 1999
Mr. Tharwat Abdelshahid, CFO, EIPICO, June 1999

Annex 2

Three Stages of Human and Clinical Testing

Preclinical testing and clinical evaluation are usually conducted before a new protein/compound is tested in humans. Laboratory and animal studies are carried out to determine their safety and biological activity. When a compound appears to have important biological activity, special tests are conducted to evaluate its safety in the major organ systems. The most important goal of preclinical studies on animals is to establish the relationship between increased doses of the drug and its toxic effects in animals. With the completion of testing the regulatory authority (FDA, EMEA) is approached to request to test the new product in humans in the clinical trials (Hansen, 1979).

The first step for of clinical testing is safety or Phase I. The goal of this phase is to establish the drug's safety and side effects profile in human beings. In most cases, about 100 health human volunteers participate in the phase I, and are administered a single dose of the drug. If the drug proves to be safe, multiple doses of the product are evaluated for safety (Hansen, 1979).

During Phase II, the efficacy of the drug becomes the prime goal of trials conducted, while safety is also tested for. The main objectives of phase II is to identify with accuracy the optimal dosage levels, dose regimen, route of administration, and exact patient type and circumstances in which the drug should be used. This phase is conducted on patients instead of healthy volunteers. The participants of phase I are usually larger than phase II trials (Hansen, 1979).

Phase III is called the statistical efficacy phase when products which display efficacy and safety in Phase II move towards larger clinical evaluation setting to verify the results. Phase III requires hundreds and sometimes thousands of patients, as it primarily targets the establishment of a statistically significant difference in the primary end point between patients on drugs and those on placebos (Hansen, 1979).

Annex 3

Macroeconomic Performance During the Study Period

The growth performance of the Egyptian economy reflected major fluctuations, with a boom-bust pattern observed throughout the study period. While the study period spans almost two decades, in presenting the macroeconomic setting it was important to briefly shed light on the 1960s, 1970s, and 1980s as each of the three decades marked important points of departure with regards shifts in economic ideology, the build-up of structural imbalances and a change in the industrial policy governing the pharmaceutical sector.

The 1960s

The 1960s was the decade which witnessed the rapid expansion in the productive capacities of the country's pharmaceutical industry. The 1960s was also the decade which saw the radical change in economic ideology from a free market economy, to a state-dominated socialist one. Following the endorsement of socialism and an etatist economic policy during the early 1960s, the growth performance of the Egyptian economy was judged to be remarkable. In 1965 GDP growth accelerating to reach 9.2 percent, up from 4.3 percent in 1960. However, the combination of excessive inward orientation, a deteriorating balance of trade, foreign exchange shortages and the burden of financing a war economy brought growth to a complete halt in the aftermath of the 1967 war with Israel, after which GDP growth significantly slowed down to less than one percent (World Bank, 2009). A modest recovery followed towards the end of the 1960s, but with GDP growth decelerating once more as a result of the October, 1973 Arab-Israeli war.

The 1970s

In 1974 the Open Door Policy (ODP) was endorsed, with socialism abandoned for a more liberal, private sector driven economic policy. During the onset of the ODP, windfall earnings from the Suez Canal, oil exports, workers' remittances, tourism and official development assistance played an instrumental role in instigating historically high rates of GDP growth in Egypt. By 1980 GDP growth accelerated to reach 10 percent, the highest rate achieved throughout the previous four decades. Growth potential was, however, stifled as a result of macroeconomic imbalances, which began to emerge towards the late 1970s and were reinforced throughout the 1980s.

The 1980s

By the mid-80s, growth slowed down to a point of stagnation as a result of Egypt's industry remaining excessively inward oriented, as well as a regional economic slowdown, which was brought about by declining oil prices (World Bank, 1998). Chronic imbalances were manifested in a rising budget deficit (23 percent of GDP in FY 1988/89), a double-digit inflation rate (average annual rate of inflation reached and average of 18.5 percent during the 1987-90 period), and a dramatic increase in the merchandise trade deficit (from USD 4 billion in 1985 to USD 7 billion in 1990). External debt surged (USD 52.2 billion in 1988), with the burden of debt service accounting for 25 percent of the total value of the Egypt's exports of goods and services (UNIDO, 1994). Average annual growth of real GDP decelerated to reach 1 percent between 1989/90 and 1992/93 (Howard,1998).

Economic reform and structural adjustment: 1990s

In recognition of mounting economic imbalances, the government initiated an economic reform and structural adjustment program (ERSAP) in 1991. Internal and external balance was achieved, and recovery followed, albeit at a relatively slow average annual GDP growth rate of 4.6 percent during the 1991-98 period.

Following a short-lived recovery period during the first half of the 1990s, the Egyptian economy was once again facing economic hardship as a result of a worsening internal and external economic environment. On the domestic front, rapid expansion in credit facilities by the banking system, large public investment in infrastructure projects, a slowdown in the reform program, coupled with an increase in the import bill, worked on slowing real GDP growth. More importantly, the export sector did not seem to have fulfilled the expectations of the early 1990s, with export volumes remaining relatively low. Foreign exchange shortages became a chronic problem towards the end of the 1990s, reflecting the weakness of the export sector and the dependency on imports of capital and intermediate goods. Between 1998 and 2001 average annual GDP growth hovered at 4 percent.

Revisiting reform: the new millennium and beyond

Sustaining high levels of GDP growth targeted at 6-7 percent annually became the prime challenge facing policy makers in Egypt. The sustainability of acceptable levels of growth became imperative to improve the standards of living, and to absorb the large number of new entrants to the Egyptian labor market (600 thousand new entrants annually).

In February 2002 at the meeting with the Consultative Group of Egypt's donors, the government promised to put in place "an appropriate flexible market-oriented exchange rate, customs reform, and an acceleration of privatization and fiscal discipline" (EIU, 2002). In other words, the government promised to re-visit the reform agenda of 1991. In June of 2004, a new government took office in Egypt, and a comprehensive reform agenda was endorsed, instigating a growth spurt which brought GDP growth to 6.8 percent in 2005/06. Key components of the reform agenda included addressing some of the binding constraints facing investment in Egypt. Significant progress has been achieved in terms of restructuring in the financial sector, the reduction of corporate and personal income taxes, reforming tax administration, prudent and more transparent management of public finance, monetary policy reform, and expanding the scope for private sector participation through streamlining investment procedures as well as the revitalization of the privatization program (IMF, 2008).

Annex 4: List of imported generics on the Egyptian pharmaceutical market

List of generic products imported from CIPLA LTD INDIA

Trade name	Generic name	Dosage form	Pack unit	Pack #	Pack price	Strength value	Strength unit
CYTOBLASTIN 10mg/10ml vial	VINBLASTINE	injection	vial	1	LE40.000	10	mg/10ml
CYTOMID 250mg tab.	FLUTAMIDE	tablet	tablets	10	LE 38.000	250	mg
METHOCIP 50mg/2ml vial	METHOTREXATE	injection	vial	1	LE14.000	50	mg/2ml
PACLTAX 30mg/5ml vial	PACLITAXEL	injection	vial	1	LE420.000	30	mg/5ml
PHOTERICIN B 50mg/15ml vial	AMPHOTERICIN B	injection	vial	1	LE55.000	50	mg/15ml
CYTOCARB 150mg/15ml vial	CARBOPLATIN	injection	vial	1	LE180.000	150	mg/15ml
NEOPHOS 200mg/15ml vial	CYCLOPHOSPHAMIDE	injection	vial	1	LE6.000	200	mg/15ml
ETOSID 100mg/5ml vial	ETOPOSIDE	injection	vial	1	LE36.000	100	mg/5ml
CYTOCARB 450mg/45ml vial	CARBOPLATIN	injection	vial	1	LE480.000	450	mg/45ml
KELFER 500mg hard gelatin caps.	DEFERIPRONE	capsule	capsules	50	LE62.000	500	mg
NEOPHOS 1000mg/50ml vial	CYCLOPHOSPHAMIDE	injection	vial	50	LE17.500	1000	mg/50ml
IFOS 1gm vial	IFOSFAMIDE	injection	vial	1	LE60.000	1	gm
NEOFLUR 250mg/5ml amp.	FLUOROURACIL	injection	ampoule	5	LE28.000	250	mg/5ml
CYTODROX 500mg caps.	HYDROXYUREA	capsule	capsules	10	LE16.000	500	mg
ONCODOX-50 50mg vial	DOXORUBICIN	injection	vial	1	LE130.000	50	mg
BLEOCIP 15I.U./vial	BLEOMYCIN	injection	vial	1	LE85.000	15	I.U.
CYTOPLATIN 10mg/20 vial	CISPLATIN	injection	vial	1	LE12.000	10	mg/20ml
CYTOPLATIN 50mg/50ml vial	CISPLATIN	injection	vial	1	LE38.000	50	mg/50ml
DOCETAX INJECTION CONCENTRATE 80mg vial	DOCETAXEL	injection	vial	1	LE350.000	80	mg
INJECTION OF MESNA 100mg/ml amp.	MESNA	injection	ampoule	10	LE50.000	100	mg/ml
ETOSID 50mg soft gelatin caps.	ETOPOSIDE	capsule	caps.& tab.	4	LE50.000	50	mg

Source: Ministry of Health, 2009

Cont. Annex 4

List of generic products imported from China

Trade name	Generic name	Dosage form	Pack unit	Pack #	Pack price	Strength value	Strength unit	Manufacturer Name
TDA 0.1g/10g oint.	FTIBAMZONE	topical ointment	gram	10	LE15.750	0.1	gm/10g	Bejing Union
D.D.B 1.5mg pillules	BIPHENYL DICARBOXYLATE	pillules	pillules	500	LE12.000	1.5	mg	Bejing Union
BIFENDATE 1.5mg tab.	BIFENDATE	pillules	tablets	500	LE6.500	1.5	mg	Guangzhou Xing Gun -
BIFENDATE 1.5mg tab.	BIFENDATE	pillules	tablets	250	LE3.500	1.5	mg	Guangzhou Xing Gun -
INTEFEN 5M.I.U. vial	INTERFERON ALFA-2a	injection	vial	1	LE70.000	5	M.I.U.	Shenyang Sunshine
INTEFEN 3M.I.U. vial	INTERFERON ALFA-2a	injection	vial	1	LE40.000	3	M.I.U.	Shenyang Sunshine
EPIAO 10000I.u./ml vial	ERYTHROPOIETIN-ALPHA	injection	vial	1	LE160.000	10000	I.U./ml	Shenyang Sunshine
EPIAO 4000I.U./ml vial	ERYTHROPOIETIN-ALPHA	injection	vial	1	LE70.000	4000	I.U./ml	Shenyang Sunshine
EPIAO 2000I.U./ml vial	ERYTHROPOIETIN-ALPHA	injection	vial	1	LE37.000	2000	I.U./ml	Shenyang Sunshine
TETANUS ANTITOXIN 1500 IU/ml	VACCINE TETANUS	injection	vial	1	LE2.500	1500	I.U./ml	Sinochem Ningbo
PENCITARD 1200000 I.U./vial	BENZATHINE PENICILLIN G	injection	vial	1	LE3.750	1.2	M.I.U.	Ncpc North Best Co

Source: Ministry of Health, 2009

Annex 5

Investment deflator for Egypt

	Investments in current prices (LE billion)	Investments in constant prices (LE billion)	Index
1992/93	29	6.2	100
1993/94	34	6.9	105
1994/95	39.1	7.3	115
1995/96	39.7	8.2	104
1996/97	47.7	9.3	110
1997/98	61.3	11.4	115
1998/99	64	11.8	116
1999/00	64.4	11.5	120
2000/01	63.6	11.3	120
2001/02	67.5	11.9	121
2002/03	68.1	11	132
2003/04	79.6	11.7	145
2004/05	96.5	13.4	154
2005/06	115.7	15.2	163
2006/07	155.3	20	166

Source: Ministry of Economic Development, 2009

Annex 6

Wholesale Price Index (1986/87=100)*

End of June	1993**	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
General Index	287.0	300.4	316.7	348.6	365.2	367.5	373.6	379.4	384.2	397.7	469.2	543.7	571.5
Farm Products	199.1	214.6	227.9	266.1	284.3	275.9	292.8	302.9	316.9	333.0	432.2	488.8	497.3
Food Stuffs	376.3	395.7	408.7	464.4	497.7	494.3	502.7	503.6	500.3	517.9	631.7	741.1	787.1
Beverages & Tobacco	265.0	265.4	272.0	294.2	298.5	298.5	325.6	325.6	328.5	328.5	340.9	394.7	405.0
Yarn &Textiles	266.6	275.0	291.7	320.6	328.2	334.3	336.5	366.2	389.3	396.4	426.3	555.4	582.6
Wearing Apparel	335.2	351.6	368.7	376.1	378.4	386.6	393.9	410.4	417.9	429.3	444.6	495.0	506.3
Leather & Footwear	347.8	355.5	363.5	363.9	388.5	388.5	388.5	386.2	395.4	404.2	425.4	500.2	526.7
Wood & its Products	278.7	283.3	310.9	313.6	314.8	315.7	317.1	311.4	310.3	311.0	401.3	470.2	407.7
Paper & Printing	283.7	284.0	365.5	389.9	390.4	400.2	339.1	356.7	354.4	354.4	409.2	452.1	488.6
Chemicals & its products	311.5	330.7	346.4	375.3	385.2	402.2	402.3	404.5	400.4	405.5	419.1	462.0	486.3
Fuel & Related Products	610.5	620.9	623.3	632.7	632.7	684.0	684.1	679.2	679.2	690.4	686.7	733.9	845.3
Rubber & Plastic Products	213.7	217.3	260.0	293.5	295.6	300.5	306.5	306.2	269.4	313.5	336.3	377.4	405.1
Nonmetallic Mineral Products	232.6	262.3	273.8	293.9	297.2	317.4	320.1	323.8	320.9	332.7	338.7	386.6	427.1
Metals	279.0	279.1	325.9	338.0	352.7	361.9	322.0	333.4	333.4	352.8	454.0	630.2	707.8
Metallic Prods.,Machinery &Equipment	271.9	279.7	284.6	293.7	301.1	308.9	314.2	306.7	308.8	317.8	348.1	389.9	408.4
Transportation Equipment	340.0	341.4	385.6	393.6	393.6	401.2	370.8	362.0	362.0	362.5	428.0	589.2	572.5
Other Manufacturing Products	204.1	209.5	214.2	227.6	346.2	344.8	358.7	398.7	399.4	426.7	486.8	503.9	614.8

* As from January 1994. The base year became 1986/87 = 100, instead of 1965/66=100.
** at End of July 1993.
Source: Central Bank of Egypt, 2009

Annex 7

Egypt Consumer price index (2000 = 100)

Year	
1987	25.50
1988	30.00
1989	36.38
1990	42.48
1991	50.87
1992	57.80
1993	64.79
1994	70.07
1995	81.10
1996	86.93
1997	90.95
1998	94.48
1999	97.39
2000	100.00
2001	102.27
2002	105.07
2003	109.81
2004	122.18
2005	128.13

Source: World Bank, 2009b

Annex 8

List of pharmaceutical companies in Egypt and their establishment dates

Company	Establishment Date	First year in operation
BMS Egypt	1974/15/12	25/03/1979
SICAM Labs	1997/24/5	28/03/1981
EIPICO	1980/18/12	14/01/1985
GSK	1980/27/2	24/04/1985
ATOS Pharma	1986/1/1	01/07/1986
PHARCO	1982/18/5	12/01/1987
J&J	1983/11/9	12/06/1988
Amiriya	1984/1/3	01/10/1988
Amoun	1988/13/12	13/12/1988
Adweya	1984/6/5	01/03/1989
Santigenta Agro	1989/22/3	22/03/1989
MUP	1984/1/1	13/09/1989
Mepaco(	1984/1/1	09/04/1990
SEDICO	1983/5/5	02/06/1990
Phizer Egypt	1973/16/10	20/08/1990
Sanofi Aventis	1973/26/1	20/08/1990
Novartis	1973/2/4	20/08/1990
Apex	1991/1/1	18/01/1991
Hikma	1990/1/12	05/11/1992
October	1987/1/1	02/02/1993
Servier Egypt	1992/28/1	19/04/1994
T3A	1994/15/6	25/07/1994
Ten of Remadan	1985/1/7	26/07/1994
Egypt Otsuka	1992/7/10	23/05/1995
Smith Kline Becham Egypt	1997/12/1	12/01/1997
Akapi Egypt	1994/4/9	22/03/1997
Global Napi	1991/1/1	11/02/1998
Egyptian European	1998/18/2	22/02/1998
Amoun Pharma	1998/17/10	17/10/1998
Elli Lilly	1995/13/6	17/03/1999
Egyptin Swiss Pharma	1998/1/2	24/04/1999
Eva	1997/19/6	27/07/1999
Delta Pharma	1997/6/12	01/09/1999
Wyth Egypt	1999/8/9	08/09/1999
Sigma	1998/10/12	25/03/2000
T3A Industrial	1997/13/11	20/02/2001
Adweya	1999/22/4	22/08/2004
Hayat	2005/10/11	10/11/2005
AstraZenka Egypt	2004/5/5	31/12/2006
EGYPHAR	2005/30/5	08/08/2007

Source: GAFI Database, 2009

Annex 9

Output, intermediate inputs, number of workers and invested capital for the sample firms (deflated)

		Output	Intermediate input	Number of Workers	Invested Capital
Alex	1993	93,880,000	52,612,974	0.001154	32,221,000
Alex	1994	97,408,979	51,154,875	0.001173	42,612,377
Alex	1995	104,229,303	55,455,988	0.001232	43,851,644
Alex	1996	109,798,562	60,064,329	0.001593	55,575,871
Alex	1997	113,314,999	55,693,942	0.001568	56,191,604
Alex	1998	113,660,324	55,360,708	0.00152	59,140,222
Alex	1999	121,956,547	60,155,784	0.001469	64,614,397
Alex	2000	130,108,429	60,340,831	0.001405	64,255,213
Alex	2001	129,937,666	65,909,926	0.001392	65,657,178
Alex	2002	133,206,004	66,977,844	0.00143	69,497,450
Alex	2003	132,044,486	62,995,421	0.001471	63,900,486
Alex	2004	130,124,068	73,581,775	0.00155	70,107,471
Alex	2005	136,234,970	73,440,792	0.00157	69,831,738

		Output	Intermediate input	Number of Workers	Invested Capital
Memphis	1993	100,524,000	62,431,020	0.001923	52,395,000
Memphis	1994	104,536,650	59,207,330	0.001874	65,702,664
Memphis	1995	107,463,004	57,674,086	0.00215	63,613,047
Memphis	1996	97,928,694	54,434,186	0.001828	77,680,625
Memphis	1997	103,924,713	52,582,797	0.001836	75,256,824
Memphis	1998	93,060,431	46,807,089	0.001687	74,784,702
Memphis	1999	98,373,760	46,946,215	0.001656	79,510,618
Memphis	2000	100,052,722	46,350,921	0.00105	77,871,515
Memphis	2001	103,120,192	49,050,068	0.001495	78,909,947
Memphis	2002	103,743,711	49,472,699	0.001484	79,417,529
Memphis	2003	103,698,803	53,223,134	0.001443	73,222,974
Memphis	2004	97,615,470	55,930,642	0.001454	76,945,446
Memphis	2005	105,245,108	58,927,243	0.001532	79,000,828

Cont. Annex 9

		Output	Intermediate input	Number of Workers	Invested Capital
Misr	1993	82,868,000	57,782,516	0.002625	34,703,000
Misr	1994	82,951,122	49,812,641	0.002407	34,400,493
Misr	1995	73,954,273	44,588,102	0.002388	37,815,548
Misr	1996	80,701,989	46,910,822	0.002311	42,595,126
Misr	1997	86,847,203	45,497,713	0.002239	39,319,623
Misr	1998	81,141,800	41,611,145	0.002201	37,862,512
Misr	1999	79,590,070	41,828,145	0.001921	37,529,026
Misr	2000	77,399,087	29,791,653	0.001718	37,294,902
Misr	2001	84,439,528	36,241,160	0.001593	37,403,109
Misr	2002	83,353,713	34,764,131	0.001544	37,013,521
Misr	2003	75,063,993	36,877,236	0.001449	34,662,219
Misr	2004	75,010,144	33,541,529	0.001572	31,851,657
Misr	2005	86,204,086	35,638,806	0.001572	33,743,834

		Output	Intermediate input	Number of Workers	Invested Capital
CID	1993	117,650,000	65,266,348	0.004193	58,271,000
CID	1994	121,016,855	71,980,386	0.003848	61,080,810
CID	1995	138,015,003	67,666,570	0.003621	64,989,333
CID	1996	135,085,424	71,900,213	0.003766	73,104,129
CID	1997	145,732,995	77,165,291	0.003855	71,522,390
CID	1998	147,480,767	73,471,959	0.003799	70,210,094
CID	1999	153,727,534	68,617,153	0.003229	77,201,113
CID	2000	151,328,163	69,838,728	0.002377	55,132,575
CID	2001	153,060,551	70,211,214	0.002284	58,382,989
CID	2002	154,730,615	70,150,811	0.002244	61,144,134
CID	2003	134,590,892	69,956,225	0.002195	57,928,774
CID	2004	143,249,545	81,210,106	0.00214	53,685,604
CID	2005	148,620,666	88,256,669	0.002435	58,245,184

Cont. Annex 9

		Output	Intermediate input	Number of Workers	Invested Capital
Nasr	1993	117,679,000	88,603,511	0.004271	97,669,000
Nasr	1994	73,129,500	74,740,794	0.00393	104,426,950
Nasr	1995	88,924,977	45,951,998	0.003866	107,356,404
Nasr	1996	113,363,424	48,952,611	0.004069	119,950,169
Nasr	1997	123,132,262	72,925,999	0.003777	114,648,491
Nasr	1998	102,157,594	75,976,259	0.003582	117,321,855
Nasr	1999	101,827,128	58,789,696	0.003049	117,688,168
Nasr	2000	103,732,965	54,047,611	0.002998	136,523,848
Nasr	2001	148,375,603	54,732,540	0.002908	154,161,608
Nasr	2002	167,504,804	89,041,824	0.00287	159,438,674
Nasr	2003	157,747,138	86,757,942	0.002863	156,761,203
Nasr	2004	147,090,705	76,756,326	0.002859	145,631,146
Nasr	2005	152,034,804	87,219,502	0.002807	139,367,301

		Output	Intermediate input	Number of Workers	Invested Capital
Nile	1993	153,673,000	99,184,685	0.003102	45,348,000
Nile	1994	167,521,441	96,072,254	0.00303	78,239,290
Nile	1995	162,785,727	90,255,661	0.002777	81,597,329
Nile	1996	159,928,233	89,828,179	0.00268	99,879,092
Nile	1997	152,359,243	81,302,891	0.00312	107,642,893
Nile	1998	153,101,243	77,530,072	0.002992	105,774,429
Nile	1999	166,144,948	81,387,595	0.002734	109,504,000
Nile	2000	170,679,667	83,874,939	0.002533	115,705,991
Nile	2001	186,279,956	94,134,727	0.002434	117,835,541
Nile	2002	171,547,774	89,846,546	0.002417	127,128,738
Nile	2003	185,328,750	89,856,208	0.00244	126,173,559
Nile	2004	176,338,667	94,565,565	0.002388	119,911,925
Nile	2005	178,380,030	85,472,792	0.002439	122,326,837

Cont. Annex 9

		Output	Intermediate input	Number of Workers	Invested Capital
Kahira	1993	112,739,000	69,995,548	0.002825	29,425,000
Kahira	1994	122,204,643	64,329,462	0.002819	31,664,781
Kahira	1995	132,853,311	71,014,476	0.002897	33,665,732
Kahira	1996	121,084,939	65,448,483	0.002943	43,485,885
Kahira	1997	132,105,274	68,014,584	0.002826	43,512,767
Kahira	1998	123,686,876	65,425,318	0.002766	49,654,370
Kahira	1999	133,859,053	68,682,603	0.002488	71,322,138
Kahira	2000	129,388,398	63,281,361	0.002476	73,570,795
Kahira	2001	130,136,827	67,574,409	0.002398	74,619,231
Kahira	2002	138,146,985	78,024,137	0.002391	76,495,105
Kahira	2003	138,587,398	74,387,273	0.002391	80,541,796
Kahira	2004	128,498,470	66,149,444	0.00231	79,178,479
Kahira	2005	142,537,993	79,172,666	0.002272	75,548,049

Cont. Annex 9

		Output	Intermediate input	Number of Workers	Invested Capital
ADCO	1993	66,309,000	44,150,824	0.0017	23,603,000
ADCO	1994	78,262,138	44,584,193	0.0016	25,408,333
ADCO	1995	73,318,503	42,959,200	0.0016	27,060,259
ADCO	1996	81,668,112	47,819,276	0.0016	30,662,616
ADCO	1997	85,612,362	44,063,695	0.0016	37,060,723
ADCO	1998	84,492,245	43,743,049	0.0019	36,216,732
ADCO	1999	92,191,766	53,614,547	0.0015	36,686,462
ADCO	2000	91,861,311	47,938,838	0.0013	37,047,667
ADCO	2001	102,029,476	50,173,065	0.0013	37,147,145
ADCO	2002	95,449,592	43,820,827	0.0012	36,528,649
ADCO	2003	89,020,174	41,072,789	0.0012	35,082,294
ADCO	2004	88,144,386	45,076,799	0.0013	34,539,134
ADCO	2005	97,461,772	49,534,127	0.0014	35,717,036

Cont. Annex 9

		Output	Intermediate input	Number of Workers	Invested Capital
SEDICO	1993	51,831,000	21,083,000	0.000328	40,818,000
SEDICO	1994	64,532,401	26,331,374	0.000353	40,607,580
SEDICO	1995	73,589,177	30,975,653	0.000429	39,840,679
SEDICO	1996	78,079,181	32,769,953	0.000494	45,820,990
SEDICO	1997	92,768,290	38,271,283	0.000513	55,632,579
SEDICO	1998	106,981,895	40,099,016	0.000612	58,581,770
SEDICO	1999	114,479,928	43,171,709	0.000654	65,287,931
SEDICO	2000	109,745,801	35,757,652	0.000741	107,861,290
SEDICO	2001	132,348,601	54,972,508	0.000795	112,106,276
SEDICO	2002	136,374,777	57,887,233	0.000835	116,083,889
SEDICO	2003	172,437,659	72,533,956	0.000864	112,196,248
SEDICO	2004	176,838,280	77,694,160	0.001022	105,855,935
SEDICO	2005	203,032,279	83,214,473	0.001087	112,265,975

		Output	Intermediate input	Number of Workers	Invested Capital
PHARCO	1993	92,500,000	49,929,019	0.000562	14,243,545
PHARCO	1994	108,982,613	60,435,075	0.000629	14,721,597
PHARCO	1995	125,445,294	67,829,877	0.000714	14,237,770
PHARCO	1996	137,282,441	72,098,328	0.000861	24,580,863
PHARCO	1997	147,986,760	72,305,426	0.000853	26,296,214
PHARCO	1998	160,551,840	73,167,753	0.001024	23,170,418
PHARCO	1999	173,287,845	77,142,571	0.001045	25,245,814
PHARCO	2000	196,911,125	79,432,838	0.001177	78,936,990
PHARCO	2001	185,235,140	93,369,206	0.001292	76,825,711
PHARCO	2002	186,746,363	95,215,468	0.001312	83,056,016
PHARCO	2003	225,430,565	115,069,188	0.001345	76,396,799
PHARCO	2004	257,493,182	132,031,933	0.001408	68,531,039
PHARCO	2005	308,112,009	145,006,533	0.001585	63,476,875

Cont. Annex 9

		Output	Intermediate input	Number of Workers	Invested Capital
EIPICO	1993	196,100,000	94,328,911	0.001451	39,986,521
EIPICO	1994	230,116,269	50,494,705	0.001511	37,598,739
EIPICO	1995	235,243,649	118,087,183	0.001547	29,473,564
EIPICO	1996	243,583,372	112,133,873	0.001623	82,939,231
EIPICO	1997	276,241,952	126,302,579	0.001743	80,360,006
EIPICO	1998	270,839,259	131,259,206	0.001882	79,023,191
EIPICO	1999	312,196,868	124,413,407	0.012237	122,218,508
EIPICO	2000	319,585,909	122,571,483	0.002039	290,745,953
EIPICO	2001	340,129,371	152,681,354	0.002138	272,173,948
EIPICO	2002	384,170,530	157,164,727	0.002249	271,311,525
EIPICO	2003	408,941,303	181,704,095	0.002274	240,028,937
EIPICO	2004	439,471,212	195,272,895	0.002549	205,959,904
EIPICO	2005	483,680,136	202,965,055	0.002745	187,256,308

		Output	Intermediate input	Number of Workers	Invested Capital
MUP	1993	54,410,000	30,583,606	0.000350	56,248,747
MUP	1994	83,766,843	42,514,668	0.000402	53,728,365
MUP	1995	113,671,362	59,577,825	0.000453	501,938,911
MUP	1996	133,969,698	64,991,198	0.000504	52,818,256
MUP	1997	149,101,400	62,666,884	0.000551	54,589,951
MUP	1998	173,395,385	70,622,112	0.000643	58,458,366
MUP	1999	188,994,795	74,121,128	0.000754	143,574,752
MUP	2000	204,852,913	73,874,532	0.000786	137,916,667
MUP	2001	229,264,819	91,792,799	0.000921	133,561,547
MUP	2002	241,456,682	98,087,277	0.000948	128,090,660
MUP	2003	248,241,126	121,973,537	0.001044	113,726,886
MUP	2004	284,341,049	125,943,481	0.009131	103,646,087
MUP	2005	324,512,517	129,191,739	0.001212	100,933,066

Cont. Annex 9

		Output Value	Intermediate inputs	Number of Workers	Invested Capital+
Amirya	1993	70,534,590	27,989,941	0.000674	35,920,936
Amirya	1994	86,176,882	29,834,361	0.000713	39,516,276
Amirya	1995	109,606,074	37,323,689	0.000816	40,745,768
Amirya	1996	116,086,920	37,948,978	0.000918	63,520,807
Amirya	1997	127,743,583	42,616,792	0.000982	81,585,663
Amirya	1998	129,966,993	38,297,765	0.001060	110,452,137
Amirya	1999	140,329,914	42,011,113	0.001191	121,709,372
Amirya	2000	145,201,691	39,222,518	0.001270	125,399,702
Amirya	2001	155,714,801	40,934,999	0.001474	106,468,283
Amirya	2002	167,533,535	47,347,868	0.001402	135,788,988
Amirya	2003	164,719,276	51,289,695	0.001440	144,004,314
Amirya	2004	160,402,440	48,316,201	0.001474	128,384,684
Amirya	2005	117,415,661	38,553,368	0.001529	119,981,585

Annex 10

TFP Growth in Manufacturing Industries in Egypt, 1980/81-2000/01

Sector / TFP Growth	1980/81-1994/85	1985/86-1990/91	1991/92-1995/96	1996/97-2000/01	1980/81-2000/01
Food Processing	-0.46	1.48	1.42	0.67	0.75
Spinning and Weaving	-0.04	0.96	1.72	0.59	0.81
Readymade Garments	0.67	2.16	1.89	0.59	1.33
Leather and Leather Products	1.61	-0.27	-0.9	1.32	0.44
Footwear	-1.25	0.62	2.44	0.77	0.65
Wood and Wood Products	0.46	-0.3	1.7	5.44	1.83
Furniture	1.72	0.75	-0.42	1.17	0.81
Paper and Printing	0.55	-0.3	1.11	1.06	0.61
Chemicals	0.96	5.39	-0.57	-0.24	1.39
Rubber, Plastic and Related Products	1.36	2.4	2.78	-0.65	1.47
Porcelain, China and Ceramics	0.1	2.33	3.01	-2.48	0.74
Glass Products	0.57	0.3	0.88	-0.14	0.4
Non-Metal Products	1.55	-1.56	-0.75	-0.92	-0.42
Steel, Iron and Metal Products	1.76	-1.29	0.85	0.02	0.34
Machinery and Equipment	-0.06	1.92	1.91	-1.38	0.6
Means of Transportation	1.29	0.86	-0.48	-0.96	0.18
Mean	0.67	0.97	1.04	0.3	0.75
Standard Deviation	0.84	1.64	0.26	0.67	0.53

Source: Galal and El-Megharbel, 2005

Annex 11

Generic-to-originator prices in Egypt for the sample molecules

Sector	Company	PRODUCT	PACK/ Strength	LAUNCH	Price per unit	Generic: Innovator	Mean price per new entrant
ANTACID							
1 OMEPRAZOLE							
IMPORTED SECTOR	ASTRAZENECA	LOSEC	ENT.FILM CAP 20 MG 14	1993	10.00		
IMPORTED SECTOR	ASTRAZENECA	LOSEC	ENT.FILM CAP 20 MG 7	2003	7.00		
PRIVATE SECTOR	AMRIYA PHARMACEUT.	GASTRAZOLE	CAPS ENTERIC 20 MG 14	1994	3.03	30	3.03
PRIVATE SECTOR	EIPICO	EPIRAZOLE	CAPS ENTERIC 20 MG 14	1994	3.14	31	3.09
PRIVATE SECTOR	PHARAONIA PH.	OMEZ	CAPS 20 MG 14	2007	0.96	10	2.38
PRIVATE SECTOR	UNITED PH.MNF.	OMISEC	CAPS 20 MG 14	2007	3.00	30	2.53
Number of companies	13						
Number of products	17						
Mean price per unit	2.52						
Generic-to-originator price in molecule (%)	25						
2 RANITIDINE							
MULTINATIONAL SECTOR	GLAXOSMITHKLINE EG	ZANTAC	FILM C.TABS 150 MG 20	1994	1.00		
MULTINATIONAL SECTOR	GLAXOSMITHKLINE EG	ZANTAC	TABS EFF 150 MG 20	1997	1.20		
PRIVATE SECTOR	MEDICAL UNION PHAR	RANITIDINE	C.TAB 150 MG 20	1989	0.63	52	0.63
PRIVATE SECTOR	UNI PHARMA	RANTIBLOCK	FILM C.CAPS 150 MG 20	2009	0.45	38	0.54
Number of companies	10						
Number of products	13						
Mean price per unit	0.61						
Generic-to-originator price in molecule (%)	61						
ANTIASTHMATIC							
3 BECLOMETASONE							
MULTINATIONAL SECTOR	GLAXOSMITHKLINE EG	BECONASE	SPRAY 50 Y 200	1996	19.0		
HOLDIPHARMA	ADCO CHIESI	CLENIL COMPOSITUM	INHA.DOSIER 50 Y /DOS 200 15 G	1985	16.0	84	16
PRIVATE SECTOR	AMOUN PHARM.CO.	BECLO	NASAL SPRAY 50 Y /DOS 200 20 ML	2006	19.0	100	17.50
Number of companies	2						
Number of products	2						
Mean price per unit	16.33						
Generic-to-originator price in molecule (%)	86						

ANTIBACTERIAL

4 AMOXICILLIN

PRIVATE SECTOR	PHARCO BMS	HICONCIL	CAPS 250 MG 12	1990	0.38		
HOLDIPHARMA	CID	AMOXYCID	CAPS 250 MG 12	1980	0.36	96	96
HOLDIPHARMA	ADCO	AMOXYCILLIN	CAPS 250 MG 12	oooo	0.23	60	78
Number of companies	5						
Number of products	6						
Mean price per unit	0.41						
Generic-to-originator price in molecule (%)	110						

5 CEFTRIAXONE

PRIVATE SECTOR	EIPICO ROCHE	ROCEPHIN	V.IM DRY 1 G 1	1988	46.00		
HOLDIPHARMA	CID T3A	CEFOTRIX T3A	V.IM/IV DRY 1 G 1	1998	30.00	65	30
PRIVATE SECTOR	PHARCO	CEFAXONE	V.IV DRY 1 G 1	2008	20.00	43	25.00
Number of companies	4						
Number of products	5						
Mean price per unit	28.00						
Generic-to-originator price in molecule (%)	61						

6 CIPROFLOXACIN

PRIVATE SECTOR	HIKMA BAYER	CIPROBAY	FILM C.TABS 500 MG 10	1997	0.22		
MULTINATIONAL SECTOR	NPE SANDOZ	SERVIFLOX	TABS 500 MG 10	1997	0.36		
PRIVATE SECTOR	EIPICO	CIPROCIN	TABS 500 MG 10	1996	0.31	88	0.31
PRIVATE SECTOR	EURO.EGY.PH.	CIPROFLOXACIN	TABS 500 MG 10	2006	0.33	93	0.32
Number of companies	6						
Number of products	6						
Mean price per unit	0.39						
Generic-to-originator price in molecule (%)	108						

ANTIDEPRESSANT

7 FLUOXETINE

IMPORTED SECTOR	ELI LILLY	PROZAC	CAPS 20 MG 14	1996	4.64		
IMPORTED SECTOR	ELI LILLY	PROZAC	TABS DISPERS 20 MG 7	2002	4.71		
HOLDIPHARMA	MISR	FLUXOTINE	CAPS 20 MG 10	1996	1.55	33	1.55
PRIVATE SECTOR	EIPICO	FLUTIN	CAPS 20 MG 14	2003	0.66	14	1.10
Number of companies	6						
Number of products	6						
Mean price per unit	1.22						
Generic-to-originator price in molecule (%)	26						

ANTIDIABETIC

8 GLIBENCLAMIDE

PRIVATE SECTOR	GLAXO EG. ROCHE	EUGLUCON	TABS 5 MG 30	1980	0.09		
PRIVATE SECTOR	PHARCO	DIABEN	TABS 5 MG 20	1988	0.10	107.142859	1.1
Number of companies	1						
Number of products	1.00						
Generic-to-originator price in molecule (%)	107						

9 METFORMIN

MULTINATIONAL SECTOR	NOVARTIS PH. EGYPT	GLUCOFORMIN	TABS 500 MG 20	2002	0.10		
MULTINATIONAL SECTOR	NOVARTIS PH. EGYPT	GLUCOFORMIN	TABS 500 MG 80	2002	0.10		
HOLDIPHARMA	NASR	METFORMIN	TABS STRIPS 500 MG 200	0000	0.10	100	
PRIVATE SECTOR	MINAPHARM MERCK	GLUCOPHAGE	FILM C.TABS 500 MG 50	2006	0.30	300	0.30
Number of companies	6						
Number of products	10						
Mean price per unit	0.14						
Generic-to-originator price in molecule (%)	138						

ANTIEPILEPTIC

10 CARBAMAZEPINE

MULTINATIONAL SECTOR	NOVARTIS PH. EGYPT	TEGRETOL	TABS C.R 200 MG 20	1991	0.80		
MULTINATIONAL SECTOR	NOVARTIS PH. EGYPT	TEGRETOL	TABS 200 MG 30	2005	0.55	69	0.19
MULTINATIONAL SECTOR	NOVARTIS PH. EGYPT	TEGRETOL	TABS 200 MG 20	1986	0.55	69	
HOLDIPHARMA	CID	TEGRAL	TABS 200 MG 10	1985	0.19	35	0.19
HOLDIPHARMA	CID	TEGRAL	TABS 200 MG 50	1985	0.19	35	0.19
IMPORTED SECTOR	MULTIAPEX PH.	CARBAPEX	TABS 200 MG 30	2008	0.60	109	0.33
Number of companies	6						
Number of products	12						
Mean price per unit	0.40						
Generic-to-originator price in molecule (%)	73						

11 PHENYTOIN

HOLDIPHARMA	NILE PFIZER	EPANUTIN	TABS 100 MG 100	2000	0.10		
HOLDIPHARMA	NILE PFIZER	EPANUTIN	CAPS 100 MG 100	1995	0.10		
PRIVATE SECTOR	NILE PFIZER	EPANUTIN	CAPS 50 MG 100	1995	0.05		
HOLDIPHARMA	ALEXANDRIA BAYER	COMITAL L	TABS 100	2000			
HOLDIPHARMA	NILE PFIZER	EPANUTIN	CAPS 100 MG 50	2000	0.24		
HOLDIPHARMA	NASR	PHENYTOIN	CAPS 100 MG 40	1998	0.15	145	0.15

HOLDIPHARMA	MEMPHIS	PHENYTOIN	CAPS 100 MG 50	2006	0.28	280	0.21
Number of companies	4						
Number of products	4						
Mean price per unit	0.25						
Generic-to-originator price in molecule (%)	246						

ANTIFUNGAL

12 FLUCONAZOLE

MULTINATIONAL SECTOR	PFIZER EGYPT	DIFLUCAN	CAPS 150 MG 1	1993	27.00		
PRIVATE SECTOR	SEDICO	FLUCORAL	CAPS 150 MG 2	1996	7.30	27	7.3
IMPORTED SECTOR	SPIMACO	FLOCAZOLE	CAPS 150 MG 1	2006	18.00	67	12.65
Number of companies	6						
Number of products	6						
Mean price per unit	12.12						
Generic-to-originator price in molecule (%)	45						

ANTIHYPERTENSIVE

13 ATENOLOL

HOLDIPHARMA	KAHIRA ASTRAZENECA	TENORMIN	TABS 50 MG 14	1993	0.47		
IMPORTED SECTOR	ASTRAZENECA EGYPT	TENORET	FILM C.TABS 50 MG /12 14	2007	0.64		
IMPORTED SECTOR	ASTRAZENECA EGYPT	TENORMIN	FILM C.TABS 50 MG 14	2007	0.57		
PRIVATE SECTOR	MUP PRODES	BLOKIUM	TABS 50 MG 15	1993	0.33	71	0.33
HOLDIPHARMA	KAHIRA	TENOTENS	TABS 50 MG 14	2008	0.43	91	0.38
Number of companies	6						
Number of products	6						
Mean price per unit	0.33						
Generic-to-originator price in molecule (%)	69						

14 CAPTOPRIL

MULTINATIONAL SECTOR	BMS EGYPT	CAPOTEN	TABS 25 MG 20	1983	0.50		
MULTINATIONAL SECTOR	BMS EGYPT	CAPOTEN	TABS 25 MG 40	2003	0.50		
HOLDIPHARMA	KAHIRA	LONTENSIN	TABS 25 MG 20	1995	0.35	70	0.35
PRIVATE SECTOR	AMOUN PHARM.CO.	HYPOPRESS	TABS 25 MG 30	2008	0.30	60	0.33
MULTINATIONAL SECTOR	GLAXOSMITHKLINE EG	CAPOTEN	TABS 25 MG 20	2008	0.50	100	0.38
MULTINATIONAL SECTOR	GLAXOSMITHKLINE EG	CAPOTEN	TABS 25 MG 40	2008	0.50	100	0.41
Number of companies	5						
Number of products	6						
Mean price per unit	0.38						
Generic-to-originator price in molecule (%)	76						

15 LOSARTAN

IMPORTED SECTOR	M.S.D.	HYZAAR	TABS 50 MG 14	1998	3.71		
IMPORTED SECTOR	M.S.D.	COZAAR	TABS 50 MG 14	1998	3.71		
PRIVATE SECTOR	SIGMA	LOZAPRESS	TABS 50 MG 14	2001	1.93	52	1.93
PRIVATE SECTOR	AMRIYA PHARMACEUT.	LOSARTAN	TABS 50 MG 10	2001	1.80	48	1.86
PRIVATE SECTOR	PHARAONIA PH.	LOSARTAN	TABS 50 MG 14	2008	1.29	35	1.67
Number of companies	5						
Number of products	9						
Mean price per unit	1.80						
Generic-to-originator price in molecule (%)	49						

16 NIFEDIPINE

HOLDIPHARMA	ALEXANDRIA BAYER	ADALAT	TABS 20 MG 30	1995	0.35		
PRIVATE SECTOR	EIPICO	EPILAT	TABS L.A 20 MG 20	1989	0.53	150	0.53
PRIVATE SECTOR	SIGMA TIBA	TENOLAT	CAPS S.R 30	2004	0.50	143	0.51
Number of companies	4						
Number of products	4						
Mean price per unit	0.46						
Generic-to-originator price in molecule (%)	133						

ANTI-INFLAMMATORY

17 DICLOFENAC

MULTINATIONAL SECTOR	NPE NOVARTIS C.H.	VOLTAREN C.H.	ENTER.C.TABS 25 MG 30	1989	0.38		
MULTINATIONAL SECTOR	NOVARTIS PH. EGYPT	CATAFLAM	C.TAB 25 MG 10	1991	0.50		
MULTINATIONAL SECTOR	NOVARTIS PH. EGYPT	CATAFLAM	C.TAB 25 MG 20	2005	0.50		
PRIVATE SECTOR	PHARCO	DECLOPHEN	TABS 25 MG 20	1991	0.23	60	0.23
PRIVATE SECTOR	DELTA	DOLPHIN-K	TABS 25 MG 20	2008	0.30	80	0.53
PRIVATE SECTOR	EIPICO	EPIFENAC	TABS 25 MG 20	2008	0.20	53	0.73
Number of companies	9						
Number of products	12						
Mean price per unit	0.30						
Generic-to-originator price in molecule (%)	80						

ANTIVIRAL

18 Acyclovir

MULTINATIONAL SECTOR	GLAXOSMITHKLINE EG	NOVIRUS	CAPS 200 MG 8	1994	1.38		
MULTINATIONAL SECTOR	GLAXOSMITHKLINE EG	ZOVIRAX	TABS 200 MG 25	1986	6.67		
PRIVATE SECTOR	SEDICO	CYCLOVIRAL	TABS 200 MG 20	1997	1.05		
Number of companies	1						

Number of products	1.00
Generic-to-originator price in molecule (%)	76

Source: IMS, 2009

Annex 12

Egypt's 42 largest therapeutic classes by market value

THERAPEUTIC CLASS	Units Y/2004 ('000)	Units Y/2005 ('000)	Units Y/2006 ('000)	Units Y/2007 ('000)	Units Y/2008 ('000)	LE Sales Y/2004 ('000)	LE Sales Y/2005 ('000)	LE Sales Y/2006 ('000)	LE Sales Y/2007 ('000)	LE Sales Y/2008 ('000)
Total market	873,498	1,013,349	1,105,487	1,209,421	1,323,496	6,279,026	7,864,763	9,319,250	10,954,963	12,565,859
M01A1 ANTIRHEUMATICS NON-S PLN	64,018	74,498	83,741	89,256	102,727	411,267	514,757	616,154	693,570	810,652
J01C1 BROAD SPECT PENICILL ORAL	28,544	32,191	37,247	39,596	39,276	270,667	340,815	423,025	512,271	563,625
N02B0 NON-NARCOTIC ANALGESICS	51,848	66,479	67,267	76,693	76,874	168,943	301,762	357,980	455,428	470,829
J01D2 CEPHALOSPORINS INJECT	11,101	14,454	18,407	22,407	27,925	137,477	175,585	230,223	293,960	355,261
J01D1 CEPHALOSPORINS ORAL	20,069	20,663	22,585	23,875	27,087	214,400	228,313	254,657	272,538	320,191
J01G1 ORAL FLUOROQUINOLONES	4,434	5,573	6,590	7,897	9,104	125,084	157,631	184,789	220,183	257,461
A10H0 SULPHONYLUREA A-DIABS	20,839	18,666	21,806	20,540	21,951	145,119	153,253	216,551	217,051	243,131
A02B2 ACID PUMP INHIBITORS	2,856	4,173	5,410	6,992	8,121	76,882	115,404	151,168	191,371	234,445
R05A0 COLD PREPARATIONS	25,937	26,114	29,378	34,820	45,928	84,931	98,589	120,191	150,544	203,257
N03A0 ANTI-EPILEPTICS	5,460	6,327	6,603	7,659	8,045	79,890	105,450	122,940	166,780	195,647
A02B1 H2 ANTAGONISTS	8,885	11,680	13,087	15,163	18,013	101,580	128,030	139,045	159,703	178,535
J01C2 BROAD SPECT PENICILL INJ	16,264	20,348	25,706	30,036	31,458	76,192	98,455	126,173	156,252	173,068
J01F0 MACROLIDES & SIMILAR TYPE	5,522	6,201	7,002	7,923	9,119	94,034	109,243	128,337	147,974	169,641
R05C0 EXPECTORANTS	27,026	28,674	30,966	29,862	34,073	103,716	118,156	137,855	138,665	162,261
A05B0 HEPATIC PROCT LIPOTROPICS	5,523	6,299	6,244	7,098	8,265	87,316	109,094	114,201	131,609	157,547
R06A0 ANTIHISTAMINES SYSTEMIC	11,433	13,070	15,190	14,730	15,978	84,508	96,454	117,061	129,164	140,947
C10A1 STATINS (HMG-COA RED)	1,408	1,733	2,252	2,872	3,333	60,777	74,415	93,765	116,632	131,268
C04A1 CEREB/PERIPH VASOTHERAPS	6,211	6,129	6,470	6,555	6,235	82,316	84,782	109,273	120,781	119,440
C07A0 BETA BLOCKING AGENT PLAIN	5,863	7,757	7,984	9,217	10,507	49,698	68,322	78,533	94,100	107,513
A03F0 GASTROPROKINETICS	7,843	9,061	10,284	11,478	13,019	54,181	66,353	76,665	87,800	106,737
A10C3 H INSUL+ANA INT+FAST ACT	4,256	6,118	6,797	7,132	6,760	45,830	71,700	89,428	99,662	101,632
A07A0 ANTI-INFECTIVE ANTIDIARR	13,120	16,882	17,523	20,833	22,148	53,530	71,536	74,910	91,073	100,439
C09B1 ACE INH COMB+A-HYP/DIURET	2,094	2,871	3,541	4,190	4,441	44,125	64,751	80,557	96,622	98,567
J05B1 VIRAL HEPATITIS PRODUCTS	111	190	286	558	1,033	11,249	15,430	29,019	57,666	95,663
S01A0 ANTI-INFECTIVES-EYE	13,578	14,753	14,834	14,703	16,779	50,862	58,291	63,544	73,904	92,227
C09A0 ACE INHIBITORS PLAIN	3,979	4,401	4,666	5,288	5,224	61,554	70,882	80,213	90,252	91,213
M02A0 TOP A-RHEUMATICS & ANALG	9,742	11,795	13,874	15,039	15,673	41,405	54,992	70,088	81,833	90,560

G03G0 GONADOTROPHINS	1,768	1,635	1,780	1,848	2,292	44,724	52,941	52,104	61,871	87,799
D11A0 OTHER DERMATOLOGICAL PREP	5,947	7,771	6,771	7,025	7,683	43,009	60,682	63,054	71,692	87,190
C08A0 CALCIUM ANTAGONISTS PLAIN	3,880	4,717	5,411	5,692	6,454	44,972	55,900	67,727	78,472	86,954
N06A4 SSRI ANTIDEPRESSANTS	1,253	1,451	1,567	1,772	2,077	35,848	46,921	57,603	68,435	85,381
M05X0 OTH MUSCULO-SKELETAL PRDS	1,290	1,900	2,045	2,762	3,283	27,865	40,980	46,424	66,267	83,658
N05A1 ATYPICAL ANTIPSYCHOTICS	528	643	783	898	1,126	30,489	44,056	56,569	65,770	83,583
C09D1 AT2 ANTG COMB C2 &/O DIU	460	658	962	1,272	1,699	22,115	31,092	46,671	63,496	81,448
A08A0 ANTIOBESITY PREPARATIONS	347	509	674	807	1,157	23,824	33,056	55,066	63,431	81,357
S01C1 OPHTH STEROID+ANTI-INFEC	5,513	6,855	7,614	9,013	9,861	35,345	49,486	54,934	70,650	79,711
B01C2 ADP RECEP ANTAG PLAT INH	90	127	229	311	391	24,707	36,253	51,092	65,062	78,017
H02A1 INJ CORTICOSTEROIDS PLAIN	9,847	9,399	11,581	11,785	14,684	42,629	51,593	60,582	67,142	76,045
D06A0 TOPICAL ANTIBACTERIALS	9,826	11,240	12,433	13,465	14,963	35,668	46,788	54,683	64,047	74,454
A09A0 DIGESTIVES INC ENZYMES	8,734	9,899	10,056	10,762	11,876	46,394	57,974	60,695	64,519	73,072
D07B3 WITH ANTIBACT/ANTIFUNGALS	6,149	8,420	9,035	10,866	13,032	32,572	46,011	49,534	59,845	72,048
M03B0 MUSCLE RELAXANTS.CENTRAL	5,548	6,526	7,293	7,822	8,262	40,444	47,330	55,250	62,260	69,854

Source: IMS, 2009

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